UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
	)	Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	)	Hon. Dan A. Polster

WEDNESDAY, APRIL 24, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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Videotaped deposition of Anna Lembke, M.D., held at the offices of Lieff Cabraser Heimann & Bernstein, LLP, 275 Battery Street, 29th floor, San Francisco, California, commencing at 8:07 a.m., on the above date, before Carrie A. Campbell, Registered Diplomate Reporter and Certified Realtime Reporter.

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VIDEOGRAPHER:
DAVID KIM,
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EXHIBITS

(Exhibits attached to the deposition.)

VIDEOGRAPHER: We are now on the record. My name is David Kim. I'm a videographer for Golkow Litigation Services.

Today's date is April 24, 2019, and the time is 8:07 a.m.

This video deposition is being held in San Francisco, California, in the matter of National Prescription Opiate Litigation, MDL Number 2804 for the US District Court, the Northern District of Ohio, Eastern Division.

The deponent is Anna Lembke.

Counsel will be noted on the stenographic record.

The court reporter is Carrie Campbell and will now swear in the witness.

ANNA LEMBKE, M.D.,

of lawful age, having been first duly sworn to tell the truth, the whole truth and nothing but the truth, deposes and says on behalf of the Defendants, as follows:

DIRECT EXAMINATION

QUESTIONS BY MR. TSAI:

Q. Good morning.

A. Good morning.

Q. Diving right in, to begin with, I just wanted to confirm, are you board certified in anesthesiology, pain medicine or hospice or palliative medicine?

A. No.

Q. Can you explain to the jury what it means to be board certified in a specialized type of medical practice?

A. To be board certified in a specialized type of medical practice means to have received a certain level of training and sat for an exam and passed that exam such that you receive the certification of that specialty.

Q. And can you explain to the jury, what does it mean to complete a residence or a fellowship in a specialized field of medical practice?

A. To complete a residency or fellowship in a specialized field of medical practice means to have spent a certain amount

of time devoted to specifically studying that specialty.

Q. Have you completed any residencies or fellowships in anesthesiology, pain medicine or hospice and palliative medicine?

A. No, I have not.

Q. In an article you wrote, you described yourself as an academic psychiatrist.

Do you recall writing that article on your CV?

MR. ARBITBLIT: Do you have a copy of it, Counsel?

MR. TSAI: I do not. It's listed on her CV.

QUESTIONS BY MR. TSAI:

Q. Do you recall authoring an article called "A Friday in the Life of a Academic Psychiatrist"?

A. Yes, I do.

Q. And that was in the journal called Academic Psychiatry?

A. Yes.

Q. Is it accurate to say that you

would hold yourself out as a psychiatrist as opposed to a pain management physician or an anesthesiologist?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would disagree with that statement because I do hold myself out as having expertise in the field of pain management, but not anesthesiology, per se.

QUESTIONS BY MR. TSAI:

Q. How many hours have you spent treating patients in palliative care, for example, for their individual pain needs?

A. I have not worked in a palliative care setting.

Q. How many patients have you diagnosed with chronic pain as another example?

A. I have diagnosed many patients with chronic pain over the years. I've been in practice for more than 20 years, seen approximately 40,000 patients over my career. I couldn't tell the exact number that I've diagnosed with chronic pain, but if I had to put a ballpark estimate, I would say

something on the order of 50 percent of my patients have some kind of chronic pain diagnosis.

Q. What is the total number of patients you've treated for their individual pain needs as opposed to addiction associated with surgeries or cancer?

MR. ARBITBLIT: Object to form.

THE WITNESS: It's difficulty for me to put an exact number on that. The majority of patients that I treat for their pain needs also have some sort of co-occurring mental health disorder, but pain is a priority in the overall treatment plan of those patients.

QUESTIONS BY MR. TSAI:

Q. So just to be clear, in your practice, you engage in primary diagnoses of patients who are complaining of pain and deciding how to treat their pain needs?

MR. ARBITBLIT: Objection.

THE WITNESS: Yes.

QUESTIONS BY MR. TSAI:

Q. What is the total number of

peer-reviewed research studies or articles you've authored in the field of anesthesiology, pain medicine or hospice and palliative medicine?

A. I've authored two peer-reviewed articles in pain medicine journals, but I have written more broadly on the issue of pain vis-à-vis the opioid epidemic, and so that more broad area would include more of my publications.

Q. And focusing on the two articles in Pain Medicine journals, what were the subject matters of those two articles?

A. The subject matter of those two articles in Pain Medicine journals had to do with perioperative management of opioid agonist treatments such as buprenorphine and methadone.

Q. Who retained you as a testifying witness in this case?

A. Lieff Cabraser Heimann & Bernstein.

Q. And do you know who they represent?

A. They represent the MDL.

Q. Can you be more specific?
A. They represent the plaintiffs in this case.
Q. And who are the plaintiffs in this case?
A. The plaintiffs are the counties and other entities who have been harmed as a result of the opioid epidemic.
Q. Which counties?
A. There are too many counties to -- I guess the bellwether counties would be Cuyahoga and Summit Counties in Ohio.
Q. Have you ever prescribed opioid medications?
A. Yes.
Q. Since when?
A. I prescribe opioid medications on a weekly basis.
Q. So when did you start prescribing opioid medications?
A. Since I obtained a DEA license.
Q. And when was that?
A. That was in 2000, 2001.
Q. Approximately how many patients do you believe you've prescribed opioid

medications to?
A. It's difficult for me to put a number on that. I've been prescribing opioid medications since I became a practicing physician, and in recent years, I prescribed more opioid medication in the treatment of opioid use disorder.
Q. Other than opioid use disorder, have you prescribed opioid medications for any other condition or indication?
A. Yes, I have. In the general practice of medicine through my career, I have prescribed other opioid medications.
Q. What conditions or indications?
A. Typically pain conditions.
Q. When you prescribe opioid medications to your patients, do you weigh the risks and benefits based on your individual patients' medical histories and conditions?
A. Yes, of course.
Q. Do you have any degrees in epidemiology?
A. No.
Q. Can you explain to the jury

what epidemiology means?
A. Epidemiology is the study of the progression of disease through a population.
Q. Did you yourself actually conduct any of the epidemiological research cited in your report regarding factors associated with the opioid crisis?
A. Yes, I did.
Q. And can you explain what research you conducted?
A. I conducted research regarding who was prescribing opioids in this country as well as who is prescribing buprenorphine for the treatment of opioid use disorder, which is relevant to the opioid epidemic more broadly.
Q. And what was the information upon which you conducted your research?
A. It was based on Medicare -- a Medicare database from 2013.
Q. Did you calculate or formulate any of your own regression models or statistical analyses in this case?
A. No, I did not.

Q. Okay. Other than the Medicare database, did you conduct any of your own epidemiological analysis of any data in this case specific to the -- strike that.
Other than the Medicare database, did you conduct any original epidemiological analysis of any data in this case?
A. Yes, I did.
Q. What data?
A. Qualitative data that I collected in preparation for writing my book, "Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop."
Q. And what do you mean by qualitative data in connection with writing your book?
A. Interviews that I conducted with patients and health care providers in an attempt to understand the progression of the opioid epidemic in our population.
Q. Okay. And other than conducting interviews in connection with writing your book, did you conduct any

quantitative analysis in connection with that?

A. No.

Q. If you were asked to design an epidemiological study and statistically analyze the data results for submission to a peer-reviewed journal, would you ask for help, or would you do that all by yourself?

MR. ARBITBLIT: Objection. Compound.

QUESTIONS BY MR. TSAI:

Q. You can answer.

A. So I don't hold myself out as a biostatistician. I work with others who have expertise in that area and together we collaboratively think about the important questions and interpret the data, so I would be intimately involved in that process, but I would not be conducting the statistical analysis by myself.

Q. What is the total amount of peer-reviewed research studies or articles you've authored in the field of epidemiology?

A. I feel like I answered that question before.

Q. What is your answer?

MR. ARBITBLIT: Object. Asked and answered.

THE WITNESS: I feel I answered that before.

QUESTIONS BY MR. TSAI:

Q. What is your answer?

MR. ARBITBLIT: You really want to do that? You want to make her go back and scroll and find the answer she gave you when you asked her about that before?

QUESTIONS BY MR. TSAI:

Q. I'm just wondering what do you consider to be an epidemiological study that you have authored?

A. Well, epidemiologic -- epidemiology is the study of progression of a disease in a population, and I have spent the last approximately 20 years studying the progression of the disease of opioid dependence and addiction in the population. And I've written widely about that and I have numerous publications, which are in my CV, and I have my book "Drug Dealer, MD: How

Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop."

MR. TSAI: I'll respectfully move to strike.

QUESTIONS BY MR. TSAI:

Q. I'll ask you, have you conducted or designed any controlled epidemiological studies yourself?

A. I did answer that question.

Q. And what is your answer?

A. Well, I already --

MR. ARBITBLIT: It's a different question.

THE WITNESS: It's a different --

MR. ARBITBLIT: It's a different question.

THE WITNESS: Okay. So I have published two articles on prescribing of opioids in this country, which is relevant to the problem of the spread of the opioid epidemic in this country.

QUESTIONS BY MR. TSAI:

Q. And in those two articles that

you singled out, did you conduct any kind of regression analysis or statistical significance calculation, multi-variant analysis, or were they more qualitative?

MR. ARBITBLIT: Objection. Compound.

THE WITNESS: So those were quantitative analyses, which I did in collaboration with my biostatistician coauthors.

QUESTIONS BY MR. TSAI:

Q. Okay. And your coauthors who were in the field of biostatistics, were they the ones who conducted the quantitative analysis?

A. My coauthors are not exclusively in the field of biostatistics, but one of the coauthors has expertise in that area and did the quantitative analysis.

Q. So you yourself did not do the quantitative analysis?

A. That is correct.

Q. Have you ever taught any courses in the field of epidemiology?

A. I teach on a regular basis to

medical students, residents and practicing physicians on the spread of the opioid epidemic in the United States, and in that sense I have taught courses on epidemiology, yes.

Q. Other than that qualitative sense, do you teach any courses in the field of epidemiology, per se?

MR. ARBITBLIT: Objection. Argumentative. Asked and answered.

THE WITNESS: I feel like I gave you an answer to that question.

QUESTIONS BY MR. TSAI:

Q. Have you ever worked or consulted for the FDA?

A. No.

Q. What is the FDA?

A. The FDA is an entity that's involved with approving drugs for medical use.

Q. Do you have any experience working on the submission of any NDA to the FDA?

A. No.

Q. Do you have any experience

working on the submission of any ANDA to the FDA?

A. No.

Q. What is an NDA?

A. I don't know.

Q. What is an ANDA?

A. I don't know.

Q. Have you ever worked on the submission -- do you have any experience working on the submission of any prescription medication marketing materials to the FDA for government approval?

A. I served on the research advisory panel of California where we reviewed studies that were being conducted in the state of California on using various investigative pharmaceuticals and my role was to assess the safety of those studies. And so in that sense I have reviewed numerous studies in the process of companies seeking FDA approval for their drug.

Q. And what was the connection in that panel to any company's marketing material?

A. Well, it wasn't marketing

material, per se.

Q. Do you have any experience regarding FDA regulations that govern pharmaceutical marketing?

A. No.

Q. Have you ever treated any person in Cuyahoga or Summit Counties for opioid addiction?

A. No.

Q. Have you ever treated any patients in Cuyahoga or Summit Counties for any medical condition related to opioids?

A. No.

Q. Have you ever been to Summit County?

A. No, but I have been to Cuyahoga County.

Q. Are you able to identify any particular individuals whose opioid addiction or overdose led to costs incurred by Cuyahoga or Summit Counties?

MR. ARBITBLIT: Object to form.

THE WITNESS: I am able to -- I have analyzed the CDC data from Ohio, including Summit and Cuyahoga

Counties, and so I can speak to the issue of the opioid epidemic in those counties.

QUESTIONS BY MR. TSAI:

Q. Is the CDC data that you are referring to specific to any particular individuals residing in those counties that allows you to identify their medical condition or the circumstances of their opioid use?

MR. ARBITBLIT: Object to form.

THE WITNESS: The CDC data is looking at individuals in aggregate, not any one individual that I could identify.

QUESTIONS BY MR. TSAI:

Q. Have you ever asked for or been provided any information specific to Cuyahoga or Summit Counties regarding individual persons whose addiction the counties contend led to costs in this case?

MR. ARBITBLIT: I'll instruct you not to answer as to that question because it involves the attorney-expert privilege.

Don't answer.
QUESTIONS BY MR. TSAI:
Q. Let me rephrase it.
Have you ever reviewed any information specific to Cuyahoga or Summit Counties regarding any actual individuals whose opioid addiction the counties contend led to the costs that they're seeking in this case?
A. Well, I have reviewed information specific to Cuyahoga and Summit Counties regarding individuals living in those counties broadly speaking as an aggregate, not any one individual. I haven't personally treated any one individual living in those counties.
Q. Well, let me ask it this way: Do you have any basis to tell us whether for any individual in Cuyahoga and Summit Counties whose opioid addiction or overdose allegedly led the counties to incur expenses, the clinical context of their opioid use?
MR. ARBITBLIT: Object to form.
THE WITNESS: Yes, I believe that I do.

QUESTIONS BY MR. TSAI:
Q. How so?
A. Well, the opioid epidemic is an epidemic that has affected every region across the United States. I have deeply studied the factors contributing to the epidemic, and it's very clear that Cuyahoga and Summit Counties are -- have been involved and have been deeply affected and harmed by the opioid epidemic and so the individual harm that has come to people living in those counties is included in the work that I have done more broadly to understand the opioid epidemic.
MR. TSAI: I'll respectfully move to strike.
QUESTIONS BY MR. TSAI:
Q. I'm asking about particular individuals who experienced opioid addiction or opioid use disorder and reside in Cuyahoga and Summit Counties.
Can you identify any single individual and tell us, for example, the severity of their pain?
MR. ARBITBLIT: Object to form.

THE WITNESS: I have not treated an individual in Cuyahoga County, but I feel that that does not preclude me from speaking to the problem of opioid addiction and overdose deaths in those counties.
QUESTIONS BY MR. TSAI:
Q. Putting aside the fact that you haven't treated any individual in Cuyahoga or Summit Counties, can you -- do you have a basis based upon any -- anything that you've written, any works that you've done, to identify for any actual individual with opioid use disorder residing in those counties the severity of that individual's pain?
MR. ARBITBLIT: Object to form. Asked and answered.
THE WITNESS: I feel like I've answered this question.
QUESTIONS BY MR. TSAI:
Q. Is the answer no?
MR. ARBITBLIT: Object to form.
THE WITNESS: The answer is yes.

QUESTIONS BY MR. TSAI:
Q. The answer -- okay. Then if the answer is yes, tell me -- give me a specific example of an individual resident in Cuyahoga and Summit County with opioid use disorder and tell me the circumstances and the extent of their pain condition at the time they used opioids?
MR. ARBITBLIT: Object to form.
THE WITNESS: The circumstances of individuals in Summit and Cuyahoga Counties mirror the circumstances of individuals across the United States vis-à-vis the opioid epidemic. There are patterns that have been replicated that apply to those individuals.
I have not personally treated an individual in Cuyahoga or Summit County, but I still believe that I can speak to and have an opinion on the problem of opioid addiction, overdose deaths of individuals in those counties.
QUESTIONS BY MR. TSAI:
Q. So to be clear, your assumption

that there are similar circumstances is not based on any treatment of any actual individual, correct?

MR. ARBITBLIT: Object to form. Argumentative. Asked and answered.

She's answered the question five different ways, and you've asked it five different ways. It's the same question.

MR. TSAI: She hasn't answered.

MR. ARBITBLIT: I disagree.

THE WITNESS: Yeah, I think I've answered it.

QUESTIONS BY MR. TSAI:

Q. What is the basis of your assumption that any particular case of opioid use disorder of a resident of Cuyahoga and Summit Counties is, as you say, similar to patterns that you refer to?

MR. ARBITBLIT: Objection. Argumentative.

THE WITNESS: I've treated many individuals with opioid use disorders over many years. The natural history and progression of the disease of

addiction is similar in every individual that I have treated.

I have no basis to believe that that would be any different for the individuals in Cuyahoga and Summit Counties.

QUESTIONS BY MR. TSAI:

Q. Did you review a single medical record related to an individual in Cuyahoga and Summit County?

MR. ARBITBLIT: Asked and answered.

She's told you she has not reviewed them, Counsel. You keep asking the same question.

QUESTIONS BY MR. TSAI:

Q. So the answer is you have not reviewed any medical records related to actual individuals in Cuyahoga and Summit Counties?

A. I have not reviewed any individual medical record.

Q. So, therefore, you don't have a basis to say that any individual with opioid use disorder in Cuyahoga and Summit Counties

had a prior or current pattern of substance abuse disorder?

MR. ARBITBLIT: Objection. Asked and answered. Argumentative.

THE WITNESS: I disagree.

QUESTIONS BY MR. TSAI:

Q. Then what is your basis?

MR. ARBITBLIT: Let's move on. If you keep asking this question, we can always call the discovery master.

MR. TSAI: You can feel free -- we can go off the record --

MR. ARBITBLIT: You're going to waste your time and keep asking the same question. It's your clock.

If you have anything else to say about it, you can.

THE WITNESS: I don't have anything else to say.

QUESTIONS BY MR. TSAI:

Q. What is your basis to extrapolate to the conclusion that any particular individual with opioid use disorder in Cuyahoga and Summit Counties did or did not have a co-occurring or preexisting

mental illness or medical condition?

MR. ARBITBLIT: Object to form. Asked and answered.

THE WITNESS: I don't have another answer.

QUESTIONS BY MR. TSAI:

Q. Are you able to identify any particular doctors who prescribed opioid medications to individuals in Cuyahoga and Summit Counties?

A. When you say "identify," do you mean you want me to produce specific names?

Q. Yes.

Are you able to -- that's what I mean by identify, yes.

A. Okay. No.

Q. Did you review any materials that would give you a basis for you to analyze or opine about what led any doctor to prescribe an opioid medication to their patients in Cuyahoga and Summit Counties?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes.

QUESTIONS BY MR. TSAI:

Q. Okay. What materials do you

have in mind?

A. I have in mind the misleading messaging that was put forward by the defendants to persuade doctors to prescribe opioids for minor and chronic pain conditions in the absence of evidence to do so.

Q. Okay. And is that also on an aggregate basis?

A. Yes.

Q. So can you identify a single doctor in Cuyahoga and Summit Counties who relied on a particular statement of any defendant in deciding to treat his or her patient with prescription opioid medications?

MR. ARBITBLIT: Object to form.

THE WITNESS: I can identify such doctors, but not by name because I don't know their names. They're individuals that I met when I was giving talks to educate physicians in the state of Ohio who reported to me as part of that teaching that I was doing that they had prescribed opioids in ways that they regretted, and that they did so because of the misleading

messaging put forward by the pharmaceutical opioid industry.

QUESTIONS BY MR. TSAI:

Q. Okay. And when you say "giving talks to educate physicians in Ohio," what are you referring to?

A. I'm going to look at my report.

Q. And I believe we've premarked your report as Exhibit 1.

A. So in April of 2018, I was the keynote speaker at Star Trauma Recovery Center at Ohio State University Medical School in Columbus, Ohio, where I spoke on the opioid epidemic.

Also in February 2019, I was the keynote speaker at an Ohio State University interprofessional summit in Columbus, Ohio, where I spoke on the issue of the opioid epidemic.

Q. And the conversations that you referred to with doctors in connection with these speeches, did you memorialize them in any way?

A. What do you mean by "memorialize"?

Q. Do you have any written records of them?

A. No.

Q. Staying with your report, you have a term called the "Tsunami Effect," capital T, capital E. And this is on page 88 of your report.

Is the Tsunami Effect a description of an outcome, or is it a causal model with predictive power?

MR. ARBITBLIT: Object to form. Compound.

THE WITNESS: The Tsunami Effect is a way of describing the impact of flooding our society with huge numbers of opioid pills leading to the harm of individuals, not just because they themselves had received an opioid prescription, but because they then had access to opioids through somebody else's prescription.

So kind of a flooding metaphor. An example would be for a teenager who decides to take his or her grandmother's pills in experimentation

and is subsequently harmed as a result of taking those pills.

QUESTIONS BY MR. TSAI:

Q. So in that example, the teenager is a person who has not been prescribed that particular opioid medication, correct?

A. In that particular example, yes.

MR. ARBITBLIT: Wait for the question before you answer.

QUESTIONS BY MR. TSAI:

Q. And in that example, the teenager has not been evaluated or advised by a physician, correct?

A. In that example, that's correct.

Q. Does the Tsunami Effect predict what individuals in particular cities and counties will become addicted to or overdose from opioids?

A. I would like to refer to my report for a moment.

Q. Do you have that?

(Lembke Exhibit 1 marked for

identification.)
QUESTIONS BY MR. TSAI:
Q. Let's go ahead and mark the report as Exhibit 1.
A. Sorry, I'm looking for that particular article that I reviewed.
Can you repeat the question?
Q. Sure.
Let me say -- ask you this in a different way, but let me back up.
Have you ever published the Tsunami Effect theory in any peer-reviewed, scientific journal?
A. Well, my book was published by Johns Hopkins University Press, and it went through a peer-review process. And although I don't believe that I used the term "the Tsunami Effect" in my book, I do discuss the more general principle of the problem of increased access to opioid medication being the major cause of this epidemic, not just for individuals directly prescribed the opioid, but for all those individuals who have increased access as a result of that prescription.

Q. Your book, "Drug Dealer, MD," is not a peer-reviewed, scientific journal, correct?
MR. ARBITBLIT: Object to form.
THE WITNESS: My book was published by an academic press, a very esteemed one, Johns Hopkins University Press, and it went through a peer-review process prior to publication, and in that sense stands out as distinct from, for example, a trade book.
QUESTIONS BY MR. TSAI:
Q. Is it your statement that the peer-review process for publication of your book is the same as a peer-review process to get an article published in a scientific journal?
A. Yes.
Q. Other than your book, have you published in any peer-reviewed, scientific journal regarding the Tsunami Effect?
A. No.
Q. Have you ever tested the Tsunami Effect theory to quantify what

persons ultimately addicted to opioids were individuals whose initial exposure was via a medically appropriate prescription of an opioid medication for a legitimate pain condition?
MR. ARBITBLIT: Object to form.
THE WITNESS: I have not done the research to quantify that. I have done the research, the qualitative research, on that.
And further, I would say that others have done research showing that there's a very intimate link between the nonmedical use of opioid pain pills and the subsequent development of addiction and the medical use of opioid pain pills.
So those are all intertwined, and I think that has been established in the literature, and it's also in my report.
QUESTIONS BY MR. TSAI:
Q. And an example of a nonmedical use of opioid pain medications is using an opioid, knowing that you're not the person

who was prescribed the medication; is that correct?
A. No.
Q. Oh, is an example of a nonmedical use of opioid pain pills to deliberately get a high as opposed to treat the pain condition?
A. No, not exclusively.
Q. Is that one example of a nonmedical use of opioids as you've referred to it?
A. That is one example.
Q. Does the Tsunami Effect include within its scope individuals who deliberately misused a prescription opioid medication knowing that the medication was not prescribed to them?
A. Yes.
Q. Does the Tsunami Effect include within its scope individuals who deliberately misused a prescription opioid medication knowing they were using it in violation of the medication's warning label?
For example, crushing a pill in order to snort the powder they made to get a

high?

MR. ARBITBLIT: Object to form.

THE WITNESS: I very much doubt that the warning label came into consideration in that context when you're dealing with a teenager who is experimenting, who has access to that pill because it was prescribed to a relative and so readily available.

QUESTIONS BY MR. TSAI:

Q. So just to be clear, individuals who deliberately misuse an opioid, for example, crushing it, snorting it, injecting, in order to get a high, those are included in your Tsunami Effect?

A. Yes.

Q. Have you ever tested the Tsunami Effect to rule out the inclusion of individuals who deliberately committed a crime in obtaining and using opioids?

MR. ARBITBLIT: Object to form.

THE WITNESS: The Tsunami Effect isn't really about whether or not that individual committed a crime.

The Tsunami Effect is really

trying to capture the very real phenomenon of flooding in our society of opioid medication as a result of misleading messaging by the defendants that led to the use of those opioids in minor and chronic pain conditions and then made them readily accessible, not just to people who were prescribed opioids, but even those not being prescribed opioids.

QUESTIONS BY MR. TSAI:

Q. And to be clear about the scope of this phenomenon, as you call it, does the Tsunami Effect include within its scope individuals who deliberately committed a crime in obtaining and using opioids?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes.

QUESTIONS BY MR. TSAI:

Q. And just in going back to our discussion about your practice of prescribing opioid medications to your patients, can you name the opioid medications that you have prescribed over the course of your career?

A. I have prescribed opioids,

Schedule II opioids, over the course of my career, probably every one that you could imagine in the course of inpatient treatment.

And I can't specifically name them because I can't recollect the specific instances.

In recent years, especially practicing as an outpatient provider, I primarily prescribe buprenorphine-naloxone in the use of opioid use disorder.

Q. Have you prescribed oxycodone?

A. Not to my recollection in certain years. There may have been instances when I temporarily took over that prescription in the case of a patient that I inherited in an effort to help them taper off of that medication, but normally I would not do that.

Normally I would collaborate with my pain colleague and advise them how to help that patient taper down to a safer dose or come off the medication, oxycodone, all together.

Q. And when you refer to a pain colleague that you would collaborate with,

what are you referring to?

A. Well, I have a courtesy appointment at Stanford University School of Medicine in the department of pain. Those courtesy appointments are given out in recognition of my expertise in the treatment of pain. I see patients within the Stanford University School of Medicine Pain Clinic. In that context, I regularly collaborate with my pain colleagues around complex patients. We have interdisciplinary team treatment meetings where we will discuss those patients in collaboration to try to come together to find the best treatment plan.

I also frequently communicate with my pain colleagues using the electronic medical records system and by telephone as we collaborate together to come up with the best treatment plan for our patients with pain.

Q. Are there any particular branded opioid medications that you can recall prescribing?

A. No.

Q. Do you recall prescribing hydromorphone?

A. I think I already answered that question.
Q. What was your answer? I don't recall.
A. I don't recall any specific pain medications that I prescribed outside of the buprenorphine-naloxone that I now prescribe regularly in my outpatient practice.
Q. Do you have any experience or expertise in regard to the prescription drug supply chain?
MR. ARBITBLIT: Object to form.
THE WITNESS: I am aware of the role of the distributors in this case. I have read the complaint. I do acknowledge their contribution to the opioid epidemic, in particular the flooding of pills in small towns that should have alerted them to a problem, which they did not take action on.
MR. TSAI: Respectfully move to strike that answer.
QUESTIONS BY MR. TSAI:
Q. Have you ever worked for a

pharmaceutical company or consulted for one?
A. No.
Q. Do you have any experience or expertise regarding the setting of DEA quotas for prescription opioid medications?
A. I'm aware of DEA quotas. I'm aware of the discussion around them vis-à-vis the opioid epidemic.
Q. Do you agree that the defendants in this case are part of the legal prescription medicine manufacturing and supply business?
MR. ARBITBLIT: Object to form.
THE WITNESS: I guess I'm not -- I don't really understand the question.
QUESTIONS BY MR. TSAI:
Q. The defendants in this case are making and selling legally approved, government-regulated medicines?
MR. ARBITBLIT: Is that a question or a statement?
QUESTIONS BY MR. TSAI:
Q. Do you agree?
A. Is that a question or a

statement?
Q. I said, do you agree with that?
A. Could you rephrase the question?
Q. The defendants in the case are making and selling legally approved, government-regulated medicines; is that correct?
A. Well, I guess I would object to the form of the question, especially the government-regulated medicine part. I think that the defendants in this case have also had a major responsibility in that process of regulation.
Q. Do you have any basis to say that defendants are selling medicines that are not legally approved?
MR. ARBITBLIT: Object to form.
THE WITNESS: Yes, the medicines are legally approved.
QUESTIONS BY MR. TSAI:
Q. Do you agree that there are multiple steps between a prescription opioid medication being approved by the government on the one hand and the effects, the

phenomenon that you call the Tsunami Effect?
MR. ARBITBLIT: Object to form.
THE WITNESS: I guess I would want to know what multiple steps you're referring to.
QUESTIONS BY MR. TSAI:
Q. Well, as you envisioned the Tsunami Effect, do you agree that for any of the prescription opioid medications that you refer to in your report -- first, it has to be submitted for FDA approval?
A. Yes.
Q. And are you familiar with what requirements must be met in order for the government to approve a prescription opioid medication as safe and effective?
A. I am familiar, but I have not been asked to opine on that aspect of the case.
Q. And in addition to approval by the Food and Drug Administration as safe and effective, do you agree that opioid medications must be approved by the DEA for manufacturing and sale?
A. Yes.

Q. Okay. And then once an opioid medication pill is made, what is your understanding of how it makes its way to an actual individual in Cuyahoga and Summit Counties for use?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, there's the production part, and then there's the distribution part where it's then transported to a pharmacy, and then the pharmacy is the dispensing agent for that pill.

QUESTIONS BY MR. TSAI:

Q. And before any individual in Cuyahoga and Summit Counties can obtain an opioid, they need to get a prescription from a doctor, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes.

QUESTIONS BY MR. TSAI:

Q. Okay. So if we could discuss one of the articles that you cite in your study.

MR. TSAI: Can we have Tab 3, the McCabe study?

QUESTIONS BY MR. TSAI:

Q. And, Dr. Lembke, you cited this on page 40 of your report.

Are you familiar -- do you recall citing the McCabe prospective study?

(Lembke Exhibit 2 marked for identification.)

MR. ARBITBLIT: Is this Exhibit 2?

MR. TSAI: Yes, the exhibit next in order, Exhibit 2.

MR. ARBITBLIT: Thank you.

THE WITNESS: Are you sure it's page 40? I think it's 39.

QUESTIONS BY MR. TSAI:

Q. So the McCabe study uses the term "NMUPO."

Do you recall that?

A. Yes.

Q. And what does the term "NMUPO" mean?

A. Nonmedical use of prescription opioids.

Q. So one example of NMUPO would mean that the individual who is taking and

ingesting the opioid was not the person who was supposed to use the prescription medicine; do you agree?

A. That's -- that is how they defined it in this paper, yes.

Q. So an example is a teenager goes into a friend of a friend's house or a neighbor's house and takes leftover prescription opioid pills that have been prescribed to that friend of a friend or neighbor but not to the teenager, correct?

A. Yes.

Q. Another example of NMUPO is that the individual who was supposed to receive the prescription for the opioid medication misused it for a nonmedical purpose to get high instead of to treat a legitimate pain condition, correct?

A. Can I see the article?

Q. It's --

A. So I'm seeing their definition of nonmedical use of prescription opioids as, quote, "taking any narcotics other than heroin on your own, that is, without a doctor telling you to take them."

Q. And in your understanding of a misuse of an opioid medication, does that include taking an opioid medication for longer periods or in higher doses or different doses than the doctor instructed you to?

A. Yes.

Q. So if you could turn to page 379 of Exhibit 2, the McCabe article, and if you could look at the right-hand column, you see the Section 3, results?

A. Uh-huh.

Q. And if you could look at the second paragraph, it says, "Among adolescents who engaged in past-year NMUPO, approximately 95 percent also used other substances and the majority simultaneously co-ingested prescription opioids with other substances, 55.2 percent."

Do you see that?

A. Yes, I do.

Q. What is your understanding of what "other substances" means?

A. Substances in the medical literature typically refers to any potential

addictive substance.

Q. So looking at that finding and the 95 percent number, am I correct that means that virtually all of the individuals who were found to be nonmedical prescription opioid users were also using other addictive substances, things like alcohol and marijuana?

A. Yes, that's what this sentence means.

Q. And it's not surprising that folks who used lots of different drugs when they were teenagers had drug problems, including opioid addiction, alcohol addiction and marijuana addiction, when they were adults; do you agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: So 90 percent of adolescents who use some sort of addictive substances -- substance during their teenager years do not go on to become persons with addiction. It's about 10 to 15 percent of those individuals will develop a substance use disorder.

My point being that adolescence is a time of experimentation where many young people will try a variety of substances. So it's not particularly surprising that these individuals have experimented with whatever substances were readily available to them. As another aspect of adolescent addiction, that adolescents have more barriers, cost barriers, transportation barriers, than adults who use substances, and so they will typically use substances that are readily available to them.

So this is not a surprise to me. This is what I'm trying to say.

QUESTIONS BY MR. TSAI:

Q. And if you turn to page 381, progressing and tracking how these teenagers, who, as you were saying, are experimenting with things that are available like alcohol and marijuana, if you look at 381 and you see 3.2?

A. Yes, I do.

Q. And the second paragraph, I'll

read the first sentence. It says, "We found that adolescents who engaged in simultaneous co-ingestion of NMUPO and other drugs had significantly greater odds of AUD, CUD, ODUD and any SUD symptoms at age 35 relative to those with had no history of NMUPO during adolescence."

Do you see that?

A. Yes, I do.

Q. Okay. And AUD stands for alcohol use disorder?

A. That's correct.

Q. CUD stands for cannabis use disorder?

A. Yes.

Q. And that's marijuana addiction?

A. That's correct.

Q. ODUD stands for what?

A. Other drug use disorder.

Q. And SUD stands for what?

A. Substance use disorder.

Q. And substance use disorder would be the aggregate and all-encompassing category of addictive substances?

A. That's right.

Q. So is it -- it's not surprising that folks who use prescription opioids -- well, strike that.

Then if you can go down to the one, two, three, four -- fifth paragraph of 3.2, the authors state another finding, and I'll read it, the first sentence. "Adolescents who indicated medical use without a history of NMUPO did not differ from adolescents with no history of medical use of prescription opioids or NMUPO in the odds of AUD, CUD, ODUD and any SUD symptoms."

Do you see that?

A. Yes, I do.

Q. And when they say "medical use," am I right to read that as the opposite of NMUPO?

Medical use is the opposite of nonmedical use of prescription opioids?

A. That's fair.

Q. So am I reading this finding correctly that it's not surprising that folks who use prescription opioids following doctor's orders and as they were supposed to when teenagers did not tend to have drug

problems when they were adults?

A. I wouldn't interpret it that way, necessarily, no.

Q. Well, doesn't it say that adolescents with medical use of prescription opioids who had no history of nonmedical use were as unlikely to have opioid addiction problems as folks who had never used prescription opioids at all when they were younger?

MR. ARBITBLIT: Object to form.

THE WITNESS: This statement doesn't necessarily mean that those who are exposed to an opioid medically are not at risk for developing addiction. There's good evidence to show that even individuals exposed to an opioid medically are at increased risk for developing an opioid use disorder, specifically an article which I cite in my report on page 40 by Schroeder, et al., shows that even very limited exposure in persons age 16 to 25 years old who received an initial opioid prescription from a

dentist, approximately 6 percent of them were later diagnosed with an opioid use disorder within a year.

My point being that there is a risk with exposure to medical use of opioids, not just to nonmedical use of opioids.

MR. ARBITBLIT: And Federal Rule 106, Rule of Completeness, Counsel, page 378 of the article you're reading from states exactly this, "Medical use of prescription opioids during adolescence is associated with greater odds of subsequent prescription opioid misuse," citing Harbaugh 2018, McCabe, 2013, and '16, and Mlech, 2015.

MR. TSAI: I object to counsel's testimony.

MR. ARBITBLIT: It's not testimony. It's the Rule of Completeness, Counsel. You should be familiar with it.

MR. TSAI: The --

QUESTIONS BY MR. TSAI:

Q. So putting aside absolute risk, and we'll talk about risk later on, but what is your -- this is a finding comparing likelihood of addictive substance use disorder in two groups, correct, adolescents who had medical use of prescription opioids, no history of nonmedical use or abuse, and adolescents who never took prescription opioids, correct?

Am I reading that correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: So to me, this -- that statement that you just read is good evidence for the Tsunami Effect. That basically because there has been increased access to opioids, including for teenagers, that has subsequently increased their risk of going on to develop some kind of substance use problem.

MR. TSAI: I move to strike.

QUESTIONS BY MR. TSAI:

Q. What is your -- what is the -- the meaning of the finding that adolescents

who indicated medical use without a history of NMUPO did not differ from adolescents when no history of medical use of prescription opioids or NMUPO in the odds of substance use disorders?

Can you tell the jury what that means, in your opinion?

A. That means comparing the risk in those two populations, they had similar risk.

Q. So I wanted to ask you -- turning back to Exhibit 1, which is your report, on page 89, you talk about hepatitis C, HIV and other infectious diseases.

Have you reviewed any data to reliably rule out the likelihood that cases of hepatitis C, HIV or other infectious diseases were caused by actions independent from opioid use?

A. No.

Q. And actions independent of opioid use that are associated or that cause infectious diseases like HIV and hepatitis C include risky sexual conduct, for example; do

you agree?
A. Yes.
Q. Have you reviewed any data to reliably rule out the likelihood that cases of hepatitis C, HIV or other infectious diseases you refer to existed prior to any opioid addiction or opioid abuse?
A. No.
Q. Do you have any -- did you conduct any analysis, or do you have any basis to quantify what percentage of cases of hepatitis C, HIV and other infectious diseases that you refer to were caused by reasons that had nothing to do with opioid use?
A. No.
Q. And just to be clear, opioid use disorder and addiction are not contagious, infectious diseases, correct?
A. I would sort of disagree with that.
Q. Is there a pathogen? Is there an opioid use pathogen?
MR. ARBITBLIT: Let her finish her answer.

THE WITNESS: There is not a pathogen, per se, but the way that opioid use disorder has spread through the population is quite similar in pattern to the way that infectious diseases spread through close contacts.
QUESTIONS BY MR. TSAI:
Q. If I touch someone who has opioid use disorder, do I get opioid use disorder?
A. No, but you also don't get HIV.
Q. If I receive a blood transfusion from someone with opioid use disorder, do I get opioid use disorder?
A. No.
MR. ARBITBLIT: Counsel, we've been going just a over an hour.
Is it time for a little break?
MR. TSAI: Sure. Off the record, please.
VIDEOGRAPHER: We're going off the record, and the time is 9:11 a.m.
(Off the record at 9:11 a.m.)
VIDEOGRAPHER: We are now going

back on the record, and the time is 9:23 a.m.
QUESTIONS BY MR. TSAI:
Q. And just one quick note: In most depositions, we don't have this handy LiveNote screen, and I've noticed that you've been hearing my questions but also reading.
If I could ask you just to listen to my questions. If you need clarification, you can certainly look, but this does -- if you kind of double up, it does take up more time.
MR. ARBITBLIT: I'll instruct you to pay no attention to that. You look at the screen. The questions are complex. It's serious litigation.
Do what you need to do to understand the question.
QUESTIONS BY MR. TSAI:
Q. So --
MR. ARBITBLIT: That's why the screen's here.
QUESTIONS BY MR. TSAI:
Q. -- let me turn to the second capitalized term in your report, "Dependence

Effect," capital D, capital E, and there you refer to individuals who become dependent on opioids independent of addiction.
That's how you defined Dependence Effect.
What is opioid dependence, in your words, independent of addiction? What does that mean?
A. So that distinction has become important with the new criteria for diagnosing a substance use disorder with the DSM-V, which -- the DSM-V was a departure from the DSM-IV in the sense that prior to the DSM-V, the criteria of physiologic tolerance and withdrawal counted toward a diagnosis of addiction.
But with the evolution to the DSM-V, that no longer counted under the specific circumstances of a patient receiving an opioid from a medical doctor and developing tolerance and withdrawal as a result of taking that medication, that opioid, under a prescription as prescribed, which de facto made it more difficult, created a higher threshold, essentially, for

diagnosing addiction with the DSM-V, but was a way of recognizing that the physiologic adaptation to opioids occurs to patients taking opioids with a medical -- with a medical prescription.

And so the DSM-V was an attempt to distinguish between those individuals who developed physiologic dependence under the care of a doctor versus those individuals who developed physiologic dependence, probably also in many instances under the care of a doctor, but also had these other behavioral components that we use to signify the problem of addiction.

Does that answer your question?

Q. So do you agree with the changes that were implemented in DSM-V's diagnostic criteria for opioid use disorder?

A. I accept those changes. I think that those -- that the physiologic dependence, so the neurobiological changes that occur in the brain as a result of physical dependence on the opioid, can't be distinguished necessarily from the neurobiological changes that happen in the

brain as a result of this concept of addiction, ala DSM-V criteria. But I appreciate that a distinct social construct was necessary to subclassify those individuals who developed physiological dependence under the care of a doctor.

I actually don't agree with the DSM-V criteria in the sense that it raised the bar for physicians to be able to diagnose the problem of opioid addiction. It's that much harder to do.

And that, along with the pseudoaddiction representation that was put forward by the defendants, has essentially made it nearly impossible to diagnose opioid use disorder addiction in the population of patients who become addicted through a doctor's prescription, which is a sizeable population.

Q. So under the prior definition of opioid use disorder, under DSM-IV, it was easier to diagnose and classify individuals as opioid addicts; is that right?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, we don't

like to use the term "addicts," because it's pejorative.

I would say, yes, it has become more difficult to diagnose opioid use disorder with the DSM-V nomenclature for those individuals who become addicted to opioids through a doctor's prescription.

QUESTIONS BY MR. TSAI:

Q. So put simply: More people would be considered a person with opioid use disorder under the prior definition than under the updated definition?

MR. ARBITBLIT: Object to form.

THE WITNESS: I believe so, yes.

QUESTIONS BY MR. TSAI:

Q. So an example is: I have kidney stones, I'm prescribed opioid medications by my doctor. I say "I need more than the originally prescribed dose to relieve my pain." I complete my course under the supervision of the doctor, and when I go off, I experience withdrawal symptoms.

Under the prior framework,

DSM-IV, would I be classified as having opioid use disorder?

MR. ARBITBLIT: Object to form. Incomplete hypothetical.

THE WITNESS: It's hard for me to make that determination based on the limited example that you gave, but according to DSM-IV criteria, if you had both physical tolerance and withdrawal, then that met a low threshold criteria for having an opioid dependence problem.

QUESTIONS BY MR. TSAI:

Q. And you agree that tolerance and withdrawal are common among all users of prescription medications, not just opioid medications?

MR. ARBITBLIT: Object to form.

THE WITNESS: I disagree with that. I think that opioids stand apart in terms of the degree to which there's tolerance, so I think tolerance is more common with opioids.

I think the dependence syndrome is more severe. The withdrawal is

more excruciating for many individuals.

So I think opioids are distinct in that regard.

QUESTIONS BY MR. TSAI:

Q. Well, putting aside qualitative degrees or extent or severity, the phenomenon of tolerance, the phenomenon of withdrawal, you do see that, for example, in antidepressants like Paxil; is that right?

MR. ARBITBLIT: Object to form.

THE WITNESS: The phenomenon of tolerance and withdrawal is seen in other addictive scheduled drugs. It's not as severe as in the case of opioids.

I would disagree that that exact same phenomenon occurs with antidepressants. There is something called a discontinuation syndrome. I've seen it rarely in my career. And it's certainly not nearly as debilitating as the opioid withdraw -- as what we see with opioid withdraw. Not even in the same universe.

QUESTIONS BY MR. TSAI:

Q. And discontinuation phenomenon, that is, when a person using an antidepressant is going off of it, is tapering off or down?

A. That's right.

Q. And they experience withdrawal?

MR. ARBITBLIT: Object to form.

THE WITNESS: They experience some physical symptoms associated with that taper process.

QUESTIONS BY MR. TSAI:

Q. So am I right that individuals -- some individuals classified as having an opioid use disorder under the prior DSM-IV framework would not be deemed to have an opioid use disorder under the current updated definition?

A. That's correct.

Q. Okay. And so in tieing your Dependence Effect phenomenon to dependence as opposed to addiction, that's a broader net; am I right?

A. Yes.

Q. It's more permissive?

MR. ARBITBLIT: Object to form.

THE WITNESS: What do you mean by "permissive"?

QUESTIONS BY MR. TSAI:

Q. Well, you said lower bar, upper bar.

So let me get -- it's a lower bar to be considered dependent in your view as opposed to addicted?

A. I would say the criteria are different. I don't think I would use lower bar versus higher bar. They're now categorized as distinct and separate phenomenon.

The point of describing the Dependence Effect is to communicate that there are more than 10 million people in this country who have taken opioids as prescribed and become physically dependent and that that's a very serious and morbid physical condition, that being dependent on opioids is not some kind of benign or easily reversible phenomenon.

Q. Does prescribing or dispensing of opioid medications always lead to

dependence?

MR. ARBITBLIT: Object to form.

THE WITNESS: Almost always, yes.

QUESTIONS BY MR. TSAI:

Q. Does it inevitably lead to dependence?

A. In the vast majority of cases, yes.

Q. Does it immediately and automatically lead to dependence?

MR. ARBITBLIT: Object to form.

THE WITNESS: Not immediately. It takes people varying degrees of time. Some people become dependent within a matter of days to weeks.

Other people can go much longer, but in the vast majority of cases, people who take opioids daily for an extended period of time become physically dependent on those opioids, such that they need more and more to get the same effect. And when they reduce their dose or stop taking them for some reason, they experience

withdrawal.

And in many cases the withdrawal is excruciating and very debilitating.

QUESTIONS BY MR. TSAI:

Q. Have you reviewed any information or conducted any analysis to quantify what individuals in the counties, Cuyahoga and Summit Counties, became opioid dependent?

MR. ARBITBLIT: Object to form.

THE WITNESS: Is this getting back to what we talked about before, this question?

QUESTIONS BY MR. TSAI:

Q. I don't think I asked about opioid dependence.

A. Okay. Can you say the question again?

Q. Have you reviewed any information or conducted any analysis to quantify what individuals in the counties, Cuyahoga and Summit Counties, became opioid dependent?

MR. ARBITBLIT: Object to form.

THE WITNESS: No. No.

QUESTIONS BY MR. TSAI:

Q. Can the Dependence Effect phenomenon predict what individuals in what particular cities or counties will become addicted to or overdose from opioids?

A. Yes.

Q. How so?

A. People who are dependent on opioids are at increased risk to suffer from overdose from those opioids, even separate from being diagnosed from opioids, and I can explain that physiology, if you would like.

It's also true that people who are opioid dependent are at very high risk to go on to meet DSM-V criteria for opioid addiction.

Q. Well, let me ask it from this angle.

Have you ever tested the Dependence Effect phenomenon to, for example, rule out the inclusion of individuals who deliberately committed a crime in obtaining and using opioids?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't understand your question.

QUESTIONS BY MR. TSAI:

Q. Have you ever tested the Dependence Effect phenomenon -- well, let me ask it this way.

Does the Dependence Effect include within its scope individuals who deliberately committed a crime in obtaining and using opioids?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes.

QUESTIONS BY MR. TSAI:

Q. Does the Dependence Effect include within its scope individuals who deliberately misused a prescription opioid medication knowing that medication was not prescribed to him or her?

A. The Dependence Effect would include anybody who has become physiologically dependent on opioids.

Q. And that would include individuals residing in Cuyahoga and Summit Counties whose exposure to opioids was via opioids that were not prescribed to them?

A. Yes.

Q. Okay. Does the Dependence Effect include within its scope individuals who deliberately misused an opioid medication knowing that they were not using it for its intended indication; for example, crushing it, snorting it for a high, for euphoria, instead of to treat an indicated pain condition?

A. Yes.

Q. So the third of your triagrid {phonetic} is the Gateway Effect, capital G, capital E.

So in -- on page 86 of your report, Exhibit 1, you describe the Gateway Effect as -- you say, "The trajectory to addiction begins with exposure." Is that right?

A. That's right.

Q. Okay. So have you ever tested -- well -- actually, strike that.

I wanted to ask one more question about the Dependence Effect.

Have you ever published the theory of the Dependence Effect in any

peer-reviewed, scientific journal?
A. I haven't -- I haven't -- I haven't specifically used that terminology, but in the JAMA article that we published on buprenorphine prescribing, we do talk about the exposure and the millions of people exposed to opioids through a medical prescription, the vast majority of whom probably are opioid dependent.
Q. And have you specifically used the terminology of the Tsunami Effect, capital T, capital E, in any peer-reviewed scientific journal?
A. No.
Q. Have you ever tested the Gateway Effect, going to the third leg, to quantify what percentage of persons ultimately addicted to illegal heroin, or fentanyl, were individuals who started out purely with no substance abuse history and whose initial exposure was via a medically appropriate prescription of an opioid medication?
MR. ARBITBLIT: Object to form.
THE WITNESS: Are you asking me

if I've personally done that quantitative research?
QUESTIONS BY MR. TSAI:
Q. Yes.
A. I have not.
Q. Have you ever used the specific terminology of the Gateway Effect and published that observation in any peer-reviewed scientific journal?
A. No.
Q. Have you ever tested the Gateway Effect phenomenon to rule out the inclusion of individuals who deliberately committed a crime in obtaining and using opioids?
A. I wouldn't rule out those individuals.
Q. Okay. So the Gateway Effect, as you envision it, as you define it, does include within its scope persons, including persons in Cuyahoga and Summit County, who deliberately committed a crime in obtaining and using opioids?
A. Yes.
Q. Does the Gateway Effect include

within its scope individuals who deliberately misused a prescription opioid medication knowing that medication was not prescribed to them?
A. Yes.
Q. Does the Gateway Effect include within its scope individuals who deliberately misused a prescription opioid medication knowing it -- knowing that they were using it contrary to its intended indication and approved indication, for example, to get a high instead of treating pain?
A. So I would like to go back and amend what I said previously about the Gateway Effect and refer to my report, which on page 86, specifically says that the Gateway Effect describes those individuals who became exposed and addicted, including individuals who turned from prescription opioids to illicit sources of opioids such as heroin.
So what I'm -- the group I'm referring to in the Gateway Effect is, in fact, those individuals who started with a medical prescription and then became addicted

through that medical prescription, as distinct from the Tsunami Effect, which is those individuals who -- which includes those individuals who used an opioid not necessarily prescribed to them.
Q. Okay. So the -- you know, the beginning bound of the set of individuals that you define as within the Gateway Effect are those individuals who received a prescription directly from a doctor?
A. Yes, and thank you for allowing me the opportunity to clarify that.
Q. So the Gateway theory posits a particular direction of events: First, prescription opioids prescribed by a doctor, and then later illegal heroin or street fentanyl addiction; is that right?
A. Not necessarily.
So that individual -- so you're right in the sense that it posits an individual who began with a prescription of an opioid from a doctor, but it -- and it could include those individuals who then turn to illicit sources of heroin, but it also includes those individuals who become

addicted in an ongoing matter -- manner using the opioids prescribed by that doctor.

Q. Have you ever tested whether the Gateway Effect is confounded by individuals who had already used heroin before prescription opioid medications?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, that's something that the McCabe article looked at, and I think one of the salient findings there is it's really the combined effect of access to nonmedical opioids, plus medical use, that confers risk. It's not one or the other in isolation, and both of those individual groups can become addicted.

So people can get addicted entirely through a medical prescription and not engage in nonmedical use. They can engage in nonmedical use and then also be exposed medically; thus compounding their risk.

QUESTIONS BY MR. TSAI:

Q. So you would rely on the McCabe study's findings in regard to those groups that you mentioned?

MR. ARBITBLIT: Object to form.

THE WITNESS: No, I'm not relying on the McCabe study findings. As I said before, I've done my own qualitative research, and I've also -- I have vast experiential knowledge of this problem from the many patients I've treated in almost, you know, two decades.

So I have seen the pattern of opioid addiction as it has occurred in those individuals.

QUESTIONS BY MR. TSAI:

Q. Does the Gateway Effect include within its scope individuals who had first used heroin before they used prescription opioids?

A. No.

Q. And how would you know for a particular person in Cuyahoga or Summit County with opioid use disorder that medical

history, that sequence?

MR. ARBITBLIT: Object to form.

THE WITNESS: There are good national data that have surveyed individuals asking them about which -- individuals who have become addicted to opioids, asking them which opioid they started with, and over 80 percent of individuals report that they started with a prescription opioid.

QUESTIONS BY MR. TSAI:

Q. And those -- that statistic includes nonmedical use of prescription opioids?

A. Yes, it does, but it also includes medical use of prescription opioids.

Q. Have you ever tested whether the Gateway Effect is confounded by individuals who had already deliberately misused or abused other drugs before any medical opioid prescription?

A. There are those cases, and I have treated those individuals, and to me that doesn't mitigate the problem of addiction through an opioid prescription.

So, for example, I've had many patients who were in recovery from an addiction to something else, who then got exposed to an opioid through a medical prescription and became addicted to that opioid or relapsed to their other substance who otherwise, I believe, would not have done so were it not for the unnecessary exposure to that opioid through a medical prescription.

Q. And individuals with a history of substance abuse, and certainly a history of diagnosed substance use disorder, are at a higher risk of substance abuse disorder; do you agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: We do know based on retrospective, epidemiologic studies that patients with a personal history of substance use disorder are at increased risk to develop an opioid addiction through a medical prescription of opioids, yes.

QUESTIONS BY MR. TSAI:

Q. So you would agree that for

individuals who reside in Cuyahoga and Summit County with opioid use disorder, an important piece of information to know is their history of substance abuse disorder and substance use history?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't really consider that that important a piece of history.

QUESTIONS BY MR. TSAI:

Q. So despite testifying that epidemiology shows that patients with a personal history of substance use disorder are at an increased risk to develop an opioid addiction through a medical prescription of opioids, you wouldn't want to know whether any particular individual in Cuyahoga and Summit Counties had such a personal history of substance abuse disorder?

MR. ARBITBLIT: Object to form. Argumentative.

THE WITNESS: To me what's much more relevant is that they're currently addicted to opioids. I don't consider their past history to

inform that problem.

Furthermore, we know that many people without a past history of addiction can get addicted to opioids through a doctor's prescription.

QUESTIONS BY MR. TSAI:

Q. Okay. And since your opinion isn't -- individual's personal history of substance use disorder is not information that you would need to know, you did not review any such information for any actual individual with opioid use disorder in Cuyahoga and Summit County; am I right?

MR. ARBITBLIT: Object to form. Object to the preface.

THE WITNESS: I did not review any individual patient's history.

QUESTIONS BY MR. TSAI:

Q. So based upon your clinical experience, can you walk us through the steps between a person receiving a prescription from a doctor for an opioid medication and the ultimate outcome of going out to a street dealer and seeking illegal, nonprescribed, nonregulated heroin or fentanyl?

How does that -- how does the Gateway Effect play out in your mind from prescription to going out into a street dealer?

MR. ARBITBLIT: Object to form. Vague. Compound.

THE WITNESS: An individual presents in a medical clinic with pain and is prescribed opioids by that doctor.

The doctor has been misled by false promotional statements on the part of defendants to believe that there are benefits to the use of opioids used long term in the treatment of pain, despite the absence of evidence for that. And that doctor has also been told that the risks are very small for addiction as long as that individual is being prescribed opioids for a pain condition.

So that well-intentioned and compassionate doctor, who is trying to do the right thing, will continue that opioid prescription and even increase

the dose over time as that patient inevitably develops tolerance.

That doctor, furthermore, having been misled by the defendants to believe that no dose is too high, will continue to escalate that dose over months to years until that patient is at dangerously high doses of opioids and at risk for all kinds of morbidity and mortality, including the risk of addiction.

And eventually that individual, who is on very high doses of opioids, has neurologic changes in their brain such that if they -- they begin to experience withdrawal often between doses, so intradose withdrawal.

They have the sensation that was validated by their doctor, but which is probably not the case, that the -- they need the opioids to treat their pain when, in fact, taking the opioids is most likely just treating withdrawal from the last dose, but the physiology and the pain of withdrawal

drives that individual to then become very preoccupied with their pain, very preoccupied with the opioids, spending more and more time at the doctor's office with pain complaints, reporting that the opioids are no longer working, because they don't work in most cases for chronic pain.

And again, the compassionate doctor, being told that no dose is too high, continues to escalate until that individual is at a very, very high dose, and that individual spends almost all of their time possibly going to the emergency room to try to get more opioids to help with their worsened pain and their withdrawal and their tolerance, to the point that that individual has developed a full-blown opioid addiction within the context of medical care.

Now, should it happen that at some point that doctor retires or that doctor gets ill and can't treat that person anymore or that individual

moves to another region or the doctor moves to another region and then that individual can no longer obtain the opioids through the prescription of that -- of that doctor, then sometimes individuals will look to alternative and illicit sources of opioids. And to their mind -- in their mind, they are treating their pain when they have also developed an opioid use disorder.

QUESTIONS BY MR. TSAI:

Q. Do you agree with -- let me know if you agree or disagree with this.

When individuals become addicted to an opioid, they remain human beings?

A. Of course I agree with that.

Q. And true or false, an opioid-addicted person is just a mindless zombie?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't even know how -- that's really offensive, and I don't even know how to respond to that.

QUESTIONS BY MR. TSAI:

Q. So you disagree with that statement?

MR. ARBITBLIT: Object to form.

THE WITNESS: I disagree with that statement.

QUESTIONS BY MR. TSAI:

Q. So at the end of the day, do you agree that a person who leaves his or her house, goes to the bad part of town, turns to a street drug dealer to buy illegal heroin has assumed an extraordinary risk?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would respectfully say that I would like to take the time to educate you about the disease of addiction, because I don't think you understand it; that people with addiction lose voluntary control over their ability to choose or not choose to use that substance; that they're driven by an intense physiologic need for the substance due to the neurobiological changes, essentially the brain damage incurred

by exposure to that substance.

QUESTIONS BY MR. TSAI:

Q. Do you agree that a person who leaves his house, goes to the bad part of town, seeks out a drug dealer and buys illegal heroin, has decided to break the law?

MR. ARBITBLIT: Object to form.

THE WITNESS: No, not at all. In fact, I don't think there's the capacity for decision-making anymore for that individual.

That individual is driven by their disease. The lying, cheating, stealing and illegal activity that comes with addiction are symptoms of the disease of addiction.

QUESTIONS BY MR. TSAI:

Q. So for an individual who has been charged with, say, a heroin-related drug crime, do you believe in your opinion that they have a defense, just to say, "Well, I've received a prescription opioid medication"?

MR. ARBITBLIT: Objection. Calls for a legal conclusion.

THE WITNESS: That's very

hypothetical. I would really want to know the details of that specific scenario.

QUESTIONS BY MR. TSAI:

Q. Okay.

A. So someone charged with a heroin crime could include a bunch of different types of heroin-related crimes.

Q. Okay. So you agree that the circumstances matter; the circumstances of an individual's use or abuse of heroin do matter in determining his or her fault?

MR. ARBITBLIT: Object to form. Calls for a legal conclusion.

THE WITNESS: I don't really understand the question.

QUESTIONS BY MR. TSAI:

Q. Okay. Do you believe if a criminal defendant who was charged in Cuyahoga and Summit County with a heroin drug crime took the stand and said, "You know, according to the Gateway theory, I'm really not at fault; it's the prescription drug companies," do you think that that was -- that's an acceptable defense?

MR. ARBITBLIT: Object to form. Calls for speculation for a legal conclusion.

THE WITNESS: I believe that if that individual has the disease of addiction, it mitigates any fault they might have in some kind of criminal litigation that they're involved in.

QUESTIONS BY MR. TSAI:

Q. Okay. And then the extent of, in your view, the mitigation of their fault, what would it depend on?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, it would depend on -- I mean, it would -- it would involve many factors. It would depend on the severity of their disease of addiction. It would depend on the severity of the crime itself.

So there would be lots of mitigating factors.

QUESTIONS BY MR. TSAI:

Q. All right. And for any individuals in Cuyahoga and Summit Counties, have you reviewed information about the

severity of their opioid-related, heroin-related crimes, fentanyl-related crimes or the degree of their opioid use disorder?

A. Not for specific individuals.

Q. Okay. So you use the term "intervention" many times in your report.

A. Okay.

Q. Do you agree that there are many points of intervention for someone using prescription opioid medications in terms of catching, monitoring the symptom of addiction after they start using the medication?

MR. ARBITBLIT: Object to form.

THE WITNESS: Who would be the person doing the intervention?

QUESTIONS BY MR. TSAI:

Q. Well, let me give you an example.

So do you agree that if a person using prescription opioid medications herself notices signs of addiction, craving, for example, she can tell her doctor?

A. I disagree that that would happen in the real world because patients who

become addicted are commonly unaware of becoming addicted. That's often the way mental illness works in general, not just for addiction but other mental illnesses as well. Because the diseased organ is the brain, we lose self-awareness and an ability to objectively see ourselves.

So in the real world, it would be unusual for a patient to present and say to her doctor, "I'm having craving."

Also I would I would argue that that term "craving" is a very loaded term. It's very stigmatized. It's in the same bucket as the term you used earlier "addicts," and patients would typically not use stigmatizing terms to refer to themselves, especially in a medical context.

I would also say that patients who are becoming addicted through a doctor's prescription have a very strong narrative around treating their pain. So they do not experience craving the way that somebody who self-identifies as addiction might talk about craving. What they experience is physical pain.

Q. Well, let's talk about someone around a person with opioid use disorder.

Do you agree that if a coworker, a parent, a sibling, a friend, other family members notice, they can intervene?

MR. ARBITBLIT: Object to form.

THE WITNESS: When you say "they can intervene," can you give an example of something that they might do?

QUESTIONS BY MR. TSAI:

Q. Sure.

If they notice signs and symptoms of opioid addiction, can they -- you'd agree they can go to the person taking the opioids and say, "I think you have a problem, we should do something about it"?

A. Yes, they could do that.

Q. You've seen that happen?

A. Yes, I have.

Q. Okay. And in your report, this is on page 95, you say, "Addiction treatment should be offered within every hospital, clinic, emergency room, jail and drug court,

et cetera, across America. Meeting patients where they are has become a mantra for the field."

So do you agree that in the lifecycle of opioid use disorder, there are many meetings points, many touch points, where opioid use disorder can be noticed, can be caught and can be treated?

MR. ARBITBLIT: Object to form.

THE WITNESS: As applies to this case of the opioid epidemic, I think it has been and continues to be extremely difficult to intervene, especially in the context of the patient with pain being prescribed opioids by a compassionate doctor and a misinformed doctor to treat their pain.

Because even as the disease of addiction evolves in that context, the patient doesn't recognize that he or she is becoming addicted, and the doctor who has been miseducated due to false promotions on the part of defendants doesn't appreciate that

patients are at high risk for addiction, even in the context of being treated for their pain.

So it makes it extremely difficult to intervene in that context compared to, for example, if that person is using heroin that they got on the street corner.

QUESTIONS BY MR. TSAI:

Q. Is one important factor in the extent or the rate of opioid use disorder the number of times folks, you know, family, friends, doctors, nurses, try to or do intervene to bring the person into treatment?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't understand your question.

QUESTIONS BY MR. TSAI:

Q. Is that an important factor --

MR. ARBITBLIT: Objection.

QUESTIONS BY MR. TSAI:

Q. -- the number of times that people try to intervene to stop or to treat the progression into opioid use disorder?

MR. ARBITBLIT: Object to form.

THE WITNESS: An important factor for what?

QUESTIONS BY MR. TSAI:

Q. For the rate of ultimate opioid use disorder or the --

MR. ARBITBLIT: Object to form. Incomplete hypothetical.

THE WITNESS: I guess I'm not -- I'm still not understanding the question. I'm sorry.

QUESTIONS BY MR. TSAI:

Q. Well, do you agree that there are many touch points where intervention could have an effect on someone with opioid use disorder?

MR. ARBITBLIT: Object to form.

THE WITNESS: I'm always hopeful that there are points where we could intervene and help a person with opioid use disorder. That's -- my entire professional life is dedicated toward helping people with addiction.

(Lembke Exhibit 3 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. So if we could get Tab 5, and this will be Exhibit 3. This is the Edlund study. I would like to ask you a few questions about that.

So just turning your attention to page 5 of the Edlund study?

A. Oh, page 5? Okay.

Q. This is one of the articles that you cite in your report, correct?

A. Yes.

Q. Okay. If you look under Results, the first paragraph, and then the third sentence I'll read.

It says, "When opioids were prescribed, low dose/acute use, 15.9 percent of total sample, and medium dose/acute use, 14.7 of total sample, were by far the most common types of opioid use, and high dose/chronic use was the least common, 0.1 percent of the total sample."

Do you see that?

A. Yes, I do.

Q. Okay. Any reason to disagree with that finding?

A. No.

Q. And then if you look at the next paragraph, the last sentence, they actually break that down and translate that into actual individuals that were part of the study.

So am I reading this right that out of the 568,640 persons in this study sample, only 23 used opioids in high doses for more than 91 days?

MR. ARBITBLIT: Misstates the record.

You're just reading it wrong, Counsel.

THE WITNESS: It says 23 out of 378 are high dose.

QUESTIONS BY MR. TSAI:

Q. So counting the number of individuals in the sample who were in the high dose/chronic subset, that's 23; am I reading that right?

MR. ARBITBLIT: That's the number with opioid use disorder, Counsel, not the number who used it.

QUESTIONS BY MR. TSAI:

Q. Oh, so it's even smaller. So 23 is the number of persons studied in the sample in the high dose/chronic subset who were found to have opioid use disorder.

Am I reading that right?

A. That's right, yes.

Q. Okay.

MR. TSAI: So can we get Tab 6, please?

(Lembke Exhibit 4 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. So exhibit next in order --

MR. ARBITBLIT: Before you move on, Counsel, for completeness, the odds ratio for those in that category was 122.45, reading from page 5, the last sentence at the bottom paragraph, "For high dose/chronic odds ratio equals 122.45, 95 percent confidence interval, 72.79 to 205.99, P value, 0.001."

MR. TSAI: For the record, I object to counsel's testimony. Again,

this is taking up time. It's inappropriate.

MR. ARBITBLIT: It's not inappropriate. It's allowed under Rule 106. Read it and tell me if you disagree after you've read it.

MR. TSAI: I think it's not allowed under the deposition protocol, and I'll reserve rights. This is the second time it's happened, so...

QUESTIONS BY MR. TSAI:

Q. So exhibit next in order is the National Academy of Sciences Engineering and Medicine study that you cited in your report.

You refer to it as the NASEM?

A. Uh-huh.

Q. Or NASEM study?

A. Yes.

Q. All right. This is a big report, but I can -- we'll certainly focus you on a particular page, which is -- if you could turn to page -- it's Bates stamped MDL_EXP_0003335. It's internal page 210 if that makes it easier.

MR. ARBITBLIT: Are you giving

copies?

THE WITNESS: 33 --

QUESTIONS BY MR. TSAI:

Q. Yeah, it's probably easier to go to the internal page number, which is 210, which is on the top, and the Bates number on the bottom is 3335.

A. Yeah.

Okay.

Q. So if you could look at the last paragraph on that page, I'll read it. It says, "It is important to acknowledge that an overwhelming majority of people who use prescription opioids do not continue to use them chronically," and it has a citation to Shah, et al., 2017, "and so are not at risk of switching to heroin."

Do you see that?

A. Uh-huh.

Q. Do you have any basis to disagree with that statement?

Well, first of all, do you agree with that statement?

A. I guess I would be curious to know what they -- how they quantified or

defined "overwhelming majority."

Q. Did you undertake any quantitative analysis of the data underlying this NASEM study that you've cited?

A. Give me a moment.

So according to Mojtabai, et al., which is in my report on page 11, I'll read, quote, "Of all opioid users in 2013 and 2014, 79.4 percent were long-term users compared with 45.1 percent in 1999 to 2000."

And then I go on to say in my own words, "The increase in long-term use is important because increased duration of use is also directly correlated with risk of addiction," at which point I cite the Edlund study, which you've given me here.

Q. Okay. Have you reviewed any of the data or conducted any of your own analysis of the information that underlies the NASEM conclusion that the overwhelming majority of people who use prescription opioids do not continue to use them chronically and so are not at risk of switching --

A. Based on --

Q. -- to using heroin?

A. Yeah. Based on my review of the literature, I would disagree with that statement, and I cited one article for you that's in my report. So I disagree with that statement.

Q. And do you have a basis based upon what the authors of the -- what the National Academy of Sciences Engineering and Medicine in 2017 base their conclusion on?

MR. ARBITBLIT: Objection. Speculation.

THE WITNESS: I did not exhaustively review which articles they reviewed to form this conclusion, but I have read over 400 articles in forming my opinion, and my opinion disagrees with that statement there.

QUESTIONS BY MR. TSAI:

Q. So you -- it's fair to say that the National Academy of Sciences and Engineering and Medicine, their view of the Gate -- what you call the Gateway phenomenon is that the minority of people using prescription opioids are at risk of switching

over to illegal street heroin?

A. As I've stated in my report, I believe that somewhere between 8 and 40 percent of individuals who are prescribed an opioid for a medical condition go on to develop an opioid use disorder.

That opioid use disorder may include individuals who continue with the prescription opioid and individuals who switched to heroin.

So, again, over -- quote/unquote "overwhelming majority," no, I would -- I guess I would want to review that Shah article and read it in more depth.

MR. TSAI: Tab 7, please.

(Lembke Exhibit 5 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. So next exhibit in order is the Muhuri article that you cite in your report. I would like to ask you a few questions about that.

So if you could turn to the first page of the Muhuri article that's been handed to you, and I first want to ask

about -- turn your attention to the abstract.

Do you see the abstract in the black box on page 1?

A. Yes, I do. I'm just trying to find it in my report.

Q. It's on page 85 --

A. Great. Thank you.

Q. -- of your report.

So I'll just read this conclusion of the authors of the Muhuri article that you cite. They state, "However the vast majority of NMPR users have not progressed to heroin use. Only 3.6 percent of NMPR initiates had initiated heroin use within the five-year period following first NMPR use."

Do you see that?

A. Yes, I do.

Q. And what is NM -- NMPR is nonmedical pain relief?

A. Reliever.

Q. Reliever?

A. Yeah.

Q. Okay. So just focusing on individuals who had used the opioid

medications they were prescribed for nonmedical reasons such as getting a high, the majority of folks who used prescription opioids nonmedically were found not to progress to heroin use.

Is that -- am I reading that finding correctly?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes.

QUESTIONS BY MR. TSAI:

Q. Okay. And do you agree with this finding?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes, I do with this finding, but I think one of the major points of the Muhuri article are that 80 percent of persons who began using heroin started with a prescription opioid.

Also, I would say that although --

QUESTIONS BY MR. TSAI:

Q. And that 80 percent figure --

MR. ARBITBLIT: Let her finish. Don't interrupt. Part of the

protocol.

THE WITNESS: It's okay.

QUESTIONS BY MR. TSAI:

Q. Great.

So the 80 percent figure, this is on page 85 of your report, those are persons, individuals, who had used prescription opioids nonmedically before initiating illegal heroin use, correct?

A. Yes, but I object to your example, if I'm allowed to object, of --

Q. You're not allowed to object.

A. Oh, I'm not allowed to?

MR. ARBITBLIT: She's allowed to finish her answer.

MR. TSAI: The lawyers are --

MR. ARBITBLIT: She's allowed to finish her answer.

THE WITNESS: Yes. So every time you've mentioned nonmedical use of prescription opioids, you've used as the example to get high, and I would say that the vast -- or a large percentage, in my experience and based on my research, are not, in fact,

using the prescription opioid to get high.

There are many forms of misuse, for example, taking more than a doctor prescribed in order to relieve pain.

So I just wanted to say that.

QUESTIONS BY MR. TSAI:

Q. If you could then turn to page 14 of the Muhuri article, and that's the internal page 14 of 15. The Bates number at the bottom is -- ends in 6042.

And do you see the section called "Discussion" on that page?

A. Yes.

Q. Okay. So if you go down to the third from the last sentence, I'll read it. "Although the findings indicate that NMPR use," again, that's nonmedical pain reliever use, "is a common step on the pathway to heroin initiation, most NMPR users do not progress to heroin use."

Do you see that?

A. Yes.

Q. Okay. And do you have any basis to disagree with that finding?

A. No.
Q. And they use the term it's "a common step on the pathway to heroin use."
What are the other steps on the pathway to heroin initiation, other than beginning with opioid -- prescription opioids?
A. Well, I would say that this specifically speaks to nonmedical use of prescription opioids, and I think medical use of prescription opioids is also a common pathway to heroin addiction.
So there are many people who take their opioids just as prescribed and get addicted in that process.
Q. Any other pathways to heroin addiction?
A. Yes. There are people who obtain heroin as their first opioid, but it's much less common than folks who start with a prescription opioid.
Q. So am I stating this conclusion correctly, that the finding of the Muhuri article that you cite is that the majority of prescription opioid nonmedical users actually

do not walk through the gateway to illegal heroin?
MR. ARBITBLIT: Object to form.
QUESTIONS BY MR. TSAI:
Q. They turn away or otherwise take another path?
A. That is what it says here, yes.
Q. Okay. So then going back to page 1, the first page of the Muhuri article, in the introduction section, if you look down to the second paragraph, the authors observe that this progression from opioid -- prescription opioid medications to illegal heroin may result simply because heroin may be cheaper or easier for them to get in some locations.
Do you see that?
A. Is that here on this first page?
Q. Yeah. It's the first page -- I'm sorry, I have a different -- right. Sorry.
It is the second page of your exhibit. The Bates number ends in 6028, and it's the first full paragraph on that page.

It says, "This progression may result simply because heroin may be cheaper or easier for them to get in some locations."
Do you see that?
A. Yes.
Q. Okay. Do you have any -- did you review any information or do any analysis to determine whether this reason for switched to illegal heroin, that it's cheaper or easier to get, whether that applied -- applies in Cuyahoga or in Summit Counties?
A. No.
Q. Okay.
MR. TSAI: Could we get Tab 8, please?
MR. ARBITBLIT: Okay. Counsel, I don't want to have a disagreement with you about this, but I don't see in our summary of the protocol anything that would overrule Federal Rule 106.
If you have something that you think prevents from me reading for the Rule of Completeness, I would like to know specifically what it is.

I don't want to do this to cause animosity. I do think, based on my own experience and the rule itself, that anything that in fairness should be read with the same document as you've brought in to evidence should be read, and that's what the Rule of Completeness, Federal Rule 106 says.
If you have something that you think specifically overrules that rule in our deposition protocol, please let me know what it is. Otherwise, I'm going to do it again, and I don't want to do it again and have a fight with you. That's not my purpose.
MR. TSAI: We have a limited time on the record. Suffice it to say, I disagree.
MR. ARBITBLIT: You can disagree, and you can reserve your rights, but I'm just going to read one sentence from the same Muhuri article that says, "There are many plausible explanations for this finding, including the Gateway theory of drug

use, that posits that the use of some drugs may expose individuals to a repertoire of biological and behavioral factors that could influence their future use of other drugs."

And that's at MDL_EXP_0006043, and you can reserve whatever rights you feel you have. But I'm trying to do this expeditiously. I think I've taken up a total of about two minutes of your time.

MR. TSAI: And not only do I reserve rights, I very much object to counsel's eating up the time on the record with his testimony and colloquy, which is prohibited under the deposition protocol expressly, so I want to move on.

Can we get Tab 8, please?

(Lembke Exhibit 6 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. So I want to talk about the Compton article that you cite in your report.

This will be exhibit next in order.

MR. TSAI: Let's get that tabbed with the exhibit number.

QUESTIONS BY MR. TSAI:

Q. So if you could turn to page 160 of the Compton article. This is a New England Journal of Medicine article that you've cited in your report. And then do you see under the right-hand column the section "Conclusions"?

A. Yeah.

Q. The second sentence, I'll read it. The authors says, "Yet although the majority of current heroin users report having used prescription opioids nonmedically before they initiated heroin use, heroin use among people who use prescription opioids for nonmedical reasons is rare, and the transition to heroin use appears to occur at a low rate."

Do you see that?

A. Uh-huh, I do.

Q. Do you have any reason to disagree with this finding in the New England Journal of Medicine?

A. I don't.

Q. Okay. So there was an interesting statement that caught my eye in your report. It was page 58. You say, "Contrary to what defendants claimed, opioid painkillers are as addictive as heroin purchased on a street corner, even when being prescribed by a doctor for a legitimate pain condition because the prescription opioids have the same addictive effects on the neurocircuitry of the brain."

Do you recall that?

A. Yes.

Q. The equivalent statement that you made, I just want to test the boundaries of that statement.

Do you agree that illegal street heroin or fentanyl, for that matter, is not clinically tested by the US FDA?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, fentanyl is available in prescription form, so I guess, what do you mean by "clinically tested"?

QUESTIONS BY MR. TSAI:

Q. I'm talking about illegal street heroin where you go out to the corner drug dealer and get illegal fentanyl that has been synthetically manufactured by the criminal gang in China, let's say.

Illegal street heroin and fentanyl, they are not clinically tested by the FDA, unlike prescription opioid medications, correct?

A. That's correct, but can I -- fine, uh-huh.

Q. Do you agree that illegal street heroin or illegal street fentanyl sold by drug dealers on the street is not approved by the FDA? It's not approved by the government?

A. I would say that both of those molecules, both heroin and fentanyl -- well, fentanyl -- a form of fentanyl is approved by the FDA and prescribed, and heroin is just morphine with two acetyl groups added.

So the point I was trying to make in my report is that when you consider the way that these prescription opioids act

on the brain compared to illicit opioids, you're dealing with identical substances, and that was the point that I was trying to make with that statement.

Q. But if we're not just talking about organic chemistry or pharmacology, you agree that it's a very different context -- illegal street heroin or fentanyl is not manufactured in a government-approved, government-audited and inspected facility, agree?

MR. ARBITBLIT: Object to form. Compound.

THE WITNESS: Street heroin or let's say street fentanyl could, in fact, include versions of fentanyl that have been FDA approved, if they were diverted from that -- from a legitimate source.

QUESTIONS BY MR. TSAI:

Q. And when you say "diverted," that means someone along the chain that -- it gets into the hands of a drug dealer on the street has committed a crime?

A. Yes.

Q. Okay. And illegal street heroin and fentanyl, it may be adulterated in who knows what ways by the dealer, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes, that's true.

QUESTIONS BY MR. TSAI:

Q. And when someone goes out into the street, goes to a dealer and pays for illegal street heroin or fentanyl, what they get is not accompanied by a detailed warning label or information about the risks and benefits, correct, of that substance?

A. Yes, but that individual may believe that they understand the risks and benefits, for example, of fentanyl because they have received it with a prescription. And so they may come with that assumption to the use of that illicit substance, you know -- they're not just diverted pills but also counterfeit pills.

So we have a whole population of individuals who have received opioids through a medical prescription who think that they understand the effect of that opioid on their body, and then if they get an

adulterated version of that on the street, that puts them at very high risk as a result of their having received it with a medical prescription.

Q. And have you reviewed any information or have any basis to say that that scenario that you've just outlined occurred with any specific individual in Cuyahoga or Summit County?

A. No, but that situation is occurring nationally, and I believe that Summit and Cuyahoga County have not been excluded from that phenomenon.

Q. Okay. And when someone goes out and buys illegal street heroin or fentanyl on the street, that's not prescribed by a doctor, not monitored by a health care provider, agree?

A. I agree.

Q. Okay. So in all those ways, you agree that prescription opioid medications are not equivalent to street heroin or street fentanyl, agree?

A. Yes.

Q. Okay. And I just want to

explore your reasoning a little bit more.

If prescription opioids and heroin are essentially equivalent in terms of strength and potency at a cellular level, that means that people who start on prescription opioids and then turn to heroin, they're not doing that in order to get a stronger high; is that correct?

If they're equal in potency; is that correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: It would really depend on the particular individual. I would say that there are instances in which that individual is not looking for a stronger opioid but just looking for an opioid to keep them from going into painful withdrawal when they can no longer get their prescription opioid as their prior source.

But it's also true that in the natural disease of addiction involves seeking out more potent forms over time, and that's not to get high.

That's to essentially avoid the debilitating pain of withdrawal.

So again, I mean, you've characterized this phenomenon repeatedly as individuals going out to get high as if this is some kind of game or pleasure-seeking for them.

These individuals have a disease of addiction, and it's not fun for them. They're trying to stave off the pain of withdrawal.

QUESTIONS BY MR. TSAI:

Q. It is a big step to go out and take the risks of obtaining unregulated, illegal street heroin and fentanyl, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: It is a big step, and it speaks to the severity of their suffering, that they're willing to take that step.

QUESTIONS BY MR. TSAI:

Q. And in determining how and whether the Gateway Effect applies in a particular individual who takes that step, it does depend on the individual circumstances,

you agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: What do you mean?

QUESTIONS BY MR. TSAI:

Q. It depends on the severity of their particular condition?

MR. ARBITBLIT: Object to form.

THE WITNESS: There would be so many variables involved in that.

QUESTIONS BY MR. TSAI:

Q. So if prescription opioids and illegal heroin in your view are equal in cellular potency and strength, then am I right that what would trigger what you call the Gateway Effect is the limitation, some limitation, in the availability of prescription opioids?

A. No.

Q. Okay. So is that one reason? Is that one, say, pathway that accounts for the Gateway Effect?

A. The limitation of prescription opioids?

Q. Yes.

A. That is theoretically possible,

and anecdotally people have reported that, but I don't think there's a lot of data yet to show that that's the case.

So, for example, in states where limits have been set on opioid prescribing, the result in those states has been actually a decrease in opioid -- prescription opioid-related overdose deaths.

There's some question as to whether in those states there may be an increase in heroin-related overdose deaths because individuals can no longer get their prescription opioids, but I think that the jury is still out on exactly what that pathway is.

Q. Okay. So you can't offer a conclusive opinion as to reliably rule out that that is a common pathway that accounts for the Gateway Effect, that being the limitation of availability of prescription opioids from a doctor?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. Correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: I guess I would say I would need to know the specifics of the case.

QUESTIONS BY MR. TSAI:

Q. Okay.

MR. ARBITBLIT: If you're ready to move on, we've been going over an hour, but if you're on same topic, please complete what you're going through.

MR. TSAI: So if I could -- can we do Tab 2?

(Lembke Exhibit 7 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. So I'll come back to this, this is your book --

A. Yes.

Q. "Drug Dealer MD." This is exhibit next in order.

And I wanted to ask you if you could turn to -- it is internal page 109. And I'll also give you the Bates number. The Bates number ends in 5643.

So if you look above the

heading "opioid refugees," there's a paragraph there, and let me just read, starting with the second to the last sentence.

"However, the relationship between doctors' prescribing patterns and the initiation of heroin use remains unclear."

Do you see that?

A. Uh-hmm.

Q. Is that still your opinion?

A. So, that was my opinion when I wrote this because there was insufficient evidence, but actually, where is that on here? Because, you know, I completed this in 2014, and it takes two years until it actually comes out.

And at the time that I wrote this, I believed that -- what I was specifically referring to there was whether or not limits on opioid prescribing would drive people to heroin use. So that's what I meant with that statement.

Q. And are you -- is it still your position that it is -- you can't offer a conclusive opinion on that question?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. That relationship?

A. I think that now I would say that my opinion has changed vis-à-vis this particular statement in the sense that this is a very general statement, that "the relationship between doctors' prescribing patterns and the initiation of heroin use remains unclear" because there's not a wealth of evidence I've reviewed showing there's a clear link between receiving an opioid prescription with a doctor and being at higher risk for progressing to heroin use.

Q. And does that evidence include the studies that we went over just now, the NASEM, the Muhuri, the Compton?

A. Yes.

Q. Okay. So going back to Compton -- do you have that article, the Compton article?

A. Yeah.

Q. If you could turn to page 156 of that article.

So in the left-hand column it's

above that heading "Break." The heading says, "Heroin use among people who use prescription opioids nonmedically."

The sentence right before that, I'll read it, it says, "Finally, these differential properties and effects are likely to interact with interindividual variability in powerful complex and in completely predictable ways so that some persons who abuse prescription opioids could find heroin less rewarding than prescription opioids similarly rewarding or even more rewarding."

Do you see that?

A. Yes, I do.

Q. And do you agree with that statement?

A. I do.

Q. All right. For any individuals in Cuyahoga and Summit Counties with opioid use disorder, did you review any information or have any other basis to say whether their, as the New England Journal of Medicine put it, individual variability was such that they found heroin less similarly or more rewarding

than prescription opioids?

A. I did not review individual cases.

Q. Okay. And if we could turn to the next page, 157, of the Compton article, and the right-hand column, there they give statistics that compare heroin use to use of other substances.

So am I reading this correctly, that heroin use over the period that was studied in the -- in this NEJM article also increased upon nonmedical users of stimulants?

A. Yes, you're reading it correctly.

Q. And what are examples of stimulants?

A. Stimulants -- nicotine is a stimulant. Methamphetamine is a stimulant. Cocaine is a stimulant.

Q. And during the same time period, heroin use also increased among users of tranquilizers, sedatives, cocaine, marijuana and alcohol, correct?

A. Yes.

Q. Okay. And the next page, 158, if you look at this first full paragraph, the first sentence, the authors conclude that, "A key factor underlying the recent increases in rates of heroin use and overdose may be the low cost and high purity of heroin."

Do you see that?

A. I do.

Q. And so am I reading that correctly that the finding is that for -- when some persons who abuse prescription opioids then subsequently initiate heroin use, the cost and availability of heroin on the street are primary factors in that process?

A. To me that statement needs to be put in the larger context of increased exposure to heroin through a medical prescription and subsequent development of opioid addiction to medical heroin -- medical opioids, that then put all of those individuals at increased risk to progress to heroin use.

So I think that that statement, as I read their intention, is that in the

broader context of the Tsunami Effect and the Gateway Effect, that then these price points will impact what opioid people will use after they've already become addicted.

Q. Do you have any basis to disagree with the statement that when some persons who abuse prescription opioids initiate heroin use, it is cost and availability of heroin that are primary factors in this process, that specific conclusion?

A. Where is that statement? Is that something else you're reading, or is that just your summary of --

Q. It is right at the bottom of that same page you're looking at.

A. Okay.

Q. And it says, "Multiple studies have examined why some persons who abuse" -- "multiple studies that have examined why some persons who abuse prescription opioids initiate heroin use indicate that the cost and availability of heroin were primary factors in this process."

Do you see that sentence?

A. Uh-huh.

Q. Do you have any basis to disagree with those studies or that conclusion?

A. I don't, except that I would add that the appetite for opioids generally in the population began with increased exposure to opioids through medical prescribing.

Q. Okay.

A. And that was more of a factor than later price points. That's my opinion.

Q. Well, if you look up one paragraph above that, it's above the heading "Break" on page 158, the New England Journal of Medicine concludes, and I'll read it, "In the context of marked increases in the rate of heroin use, it is important to note that only a small percentage of nonmedical users of prescription opioids initiate heroin use."

Do you see that?

A. Uh-huh.

Q. And they go on to cite the Muhuri study that we discussed that found a rate of 3.6 percent of nonmedical

prescription opioid users that then turn to heroin use.

Do you see that?

A. Uh-huh.

Q. And they also cite the Jones study, which has a similarly low number, 4.2 percent, of persons who had used prescription opioids nonmedically then turn to heroin use.

Do you see that?

A. (No response.)

Q. And do you have any basis to disagree with those data?

A. I'm not disagreeing with those data, but I think it would be important to look at actual numbers, not just percentages, because when looking at actual numbers of people who are using opioids nonmedically who progress to heroin use, it gets to be very high numbers.

Q. Okay. And Compton talks about the aggregate big picture. So at the very bottom of that same paragraph, the NEJM article states, "Yet taken in total, the available data suggests that nonmedical

prescription opioid use is neither necessary nor sufficient for the initiation of heroin use and that other factors are contributing to the increase in the rate of heroin use and related mortality."

Do you agree with that statement?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would say that I agree that it's neither necessary nor sufficient, but it has been a huge factor in the last two decades, three decades, among individuals who use heroin as evidenced by survey studies showing that 80 percent of people who use heroin began with a prescription opioid.

QUESTIONS BY MR. TSAI:

Q. And they use that nonmedically, that figure?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. Correct?

A. Let me look at that.

My reading of that article is

that it wasn't just individuals who had used prescription opioids nonmedically. It was -- also included individuals who had received an opioid through a medical prescription.

Q. And if that was the case, that is what you would have stated in your report, if it encompassed both medical use, appropriate medical use, and nonmedical use?

MR. ARBITBLIT: Object to form.

THE WITNESS: Give me a moment. Let me find it in my report.

MR. TSAI: Can we go off the record while the witness is looking through?

VIDEOGRAPHER: Okay. Should we?

MR. ARBITBLIT: Yes.

VIDEOGRAPHER: We're now going off the record, and the time is 10:47 a.m.

(Off the record at 10:47 a.m.)

VIDEOGRAPHER: We are now going back on the record, and the time is 10:49 a.m.

QUESTIONS BY MR. TSAI:

Q. So we talked about necessary and sufficient in the Compton article.

So am I right that not sufficient -- "nonmedical prescription opioid use is not sufficient for the initiation of heroin use."

What that means is that not every person who engages in nonmedical prescription opioid use turns or -- turns to or becomes addicted to illegal heroin.

That's what "not sufficient" means, agree?

A. Yes, I agree.

Q. And "not necessary," in this context of this finding, means that individuals who become -- who develop an addiction to or overdose from illegal heroin can and are driven to heroin due to reasons that are different from prior use of prescription opioids, agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: Let me read the last part of this.

When you say "are driven to

heroin use due to reasons that are different from prior use of prescription opioids," can you explain that, what you mean by that?

QUESTIONS BY MR. TSAI:

Q. Sure.

The Compton article expressly refers to other factors that are contributing to the increase in the rate of heroin use and related mortality.

So do you acknowledge and agree that there are factors other than prescription opioid use that are contributing to the Gateway Effect increase in the rate of heroin use and related mortality?

A. Yes, I do.

Can I go back to something earlier? Just the -- I did find the article in my report, the Cicero article.

Q. Actually, I think the way this works is Don can do redirect at the end.

A. Okay.

Q. And I'm sure he'll pick up on that.

So let me ask again: They use

the term "it is not necessary."

So "not necessary" means that individuals who are addicted to or overdose from illegal heroin can develop that condition, that outcome, because of reasons that are different from prior use of prescription opioids?

A. I guess I'm struggling a little bit with your phrasing of "reasons that are different," and I know you tried to define that, but I think it's -- when I hear reasons that are different, I want to make sure that I'm, you know, answering precisely.

It seems like you're implying that somehow those people are different or their lives are different or their -- there's something fundamentally different about them, and I wouldn't agree with that.

I would say that, you know, the disease of addiction and how it progresses in a human being is really pretty similar across the board. There aren't really shocking differences independent of what the substance is.

Q. Well, you agree that the

outcome of heroin use, taking that as the end point, prescription opioid use is not necessary for that to occur?

A. Yes, I agree with that.

Q. Okay. And you agree that there's not a straight line, one-to-one relationship between individuals who are prescribed opioid medications on the one hand and individuals who are addicted to illegal street heroin and fentanyl?

A. I would disagree with that.

Q. Isn't that what the Compton article says, though?

MR. ARBITBLIT: Object to form.

THE WITNESS: No. So what you said is would you "agree that there is not a straight line, one-to-one relationship between individuals who are prescribed opioid medications on the one hand and individuals who are addicted to illegal street heroin and fentanyl."

And I would say that there is a straight line between individuals who are prescribed opioid medications and

those who get addicted to illegal street heroin and fentanyl.

It's not the only path, but there is a very clear path between those things.

QUESTIONS BY MR. TSAI:

Q. Okay. Well, could you turn back to the Edlund article? And page 7 of this. So it's the last full paragraph on page 7 of the Edlund article, I believe.

And the second sentence says, "In particular, pathways to OUDs may involve several steps, moving from low dose/acute dose to high dose/chronic use."

Do you see that?

A. Yes, I do.

Q. Do you agree that there, an individual, who ultimately develops an opioid use disorder with respect to illegal heroin, takes many steps to get to that outcome?

MR. ARBITBLIT: Object to form.

THE WITNESS: What I would say to that is that one of the most salient findings in the Edlund article is that the biggest predictor of

developing an opioid use disorder was dose and duration of the opioid far exceeding risks related to personal past history of substance use or co-occurring mental illness.

So that to me is a powerful finding because it says that although people are different and they have different life factors, that what really predicted progression -- what really predicts progression among patients treated for chronic pain with an opioid is how high their dose is and how long they're prescribed it.

QUESTIONS BY MR. TSAI:

Q. Well, if you could turn to the next page of Edlund, page 8.

So the second full sentence at the top of the page, it states, "Evidence to date suggests this is largely a self-selection process by the patients where most patients started on opioid therapy choose not to continue on to chronic use."

Do you see that?

A. Uh-huh.

Q. So just taking a step back: Do you agree that individuals who are taking prescription opioid medications are still capable of making choices, including, as Edlund observes, choosing not to continue on to chronic use?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think the use of the term in this sentence "self-selection" is a poor choice of words because people who develop the disease of addiction do lose volitional control over their choices, such that they do actually, in many instances, lack capacity to choose to continue or not continue with their opioid.

QUESTIONS BY MR. TSAI:

Q. So do you disagree with the authors of this study that you cite in using the word "choose"?

MR. ARBITBLIT: Object to form.

THE WITNESS: No.

I agree with the authors of this study, but if you want to focus

on this one particular sentence, I disagree with the language that they have used in this sentence to describe the process of progressing to addictive use in the context of receiving an opioid prescription from a doctor.

QUESTIONS BY MR. TSAI:

Q. Addiction is a disease that takes time to manifest and develop; do you agree?

A. In most cases, yes. Not in all, but in most cases.

Q. And can we agree that not every person who takes a prescription opioid medication immediately becomes addicted?

A. Yes, I agree with that.

Q. And we can agree that not every person who takes a prescription opioid medication inevitably becomes addicted?

A. It would really depend on which definition of addiction you're using.

If you're using the DSM-IV definition that includes physiologic dependence, then I think the vast majority

will inevitably become physiologic dependent on that opioid, and using the old nomenclature, they would meet criteria for opioid addiction.

Q. Is it your opinion that if any person develops a dependence on a prescription opioid, then it's game over; they're dependent for the rest of their lives?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, I would hate to say "game over," you know, in any clinical context. And they are dependent until they get off and recover their original state, assuming that they're able to do that. In many cases, they're not able to do that.

QUESTIONS BY MR. TSAI:

Q. So to the extent an individual using prescription opioids starts on a path to tolerance, dependence or opioid usage disorder, that can be reversed; you agree?

A. Yes, I do.

MR. TSAI: Okay. Let's take a break.

MR. ARBITBLIT: Okay. Well, before we take a break, under Rule 106 which says that "if a party introduces all or a part of a writing or recorded statement, an adverse party may require the introduction at that time of any other part or any other writing or recorded statement that in fairness ought to be considered at the same time."

I'm not aware of anything in the protocol that would overrule the federal rules, and I haven't been advised of such at this deposition.

And from the Compton study that counsel introduced at page 155, I will introduce the following under Rule 106. "Heroin is pharmacologically similar to prescription opioids. All these drugs produce their action through endogenous opioid systems that regulate a wide range of functions through three major types of G protein coupled receptors, mu, delta and

kappa, with particularly potent agonist activity at the mu receptor and weak activity at the delta and kappa receptors."

At page 156, just above the sentence that counsel read, the following appears, "Several prescription opioids such as hydromorphone, fentanyl, morphine and oxycodone have a potential for abuse that is similar to and in some cases even higher than the potential for abuse with heroin."

At page 157 of the same article, "A recent study with data through 2013 showed that prescription opioid abuse or dependence was associated with the likelihood of heroin abuse or dependence that was 40 times as great as the likelihood with no prescription opioid abuse or dependence even after accounting for sociodemographic, geographic and other substance abuse or dependence characteristics.

"These studies suggest a clear link between nonmedical use of prescription opioids and heroin use, especially among persons with frequent, nonmedical use, or those with prescription opioid abuse or dependence."

And finally, at page 158, "Of note, given the large number of nonmedical users, even a small percentage who initiate heroin use translates into several hundred thousand new heroin users."

We can take a break.

MR. TSAI: This is absolutely abuse of process, and it -- I think collectively we've been in dozens of these. This has never occurred before, Don.

Will you agree to give me a minute-for-minute allocation?

MR. ARBITBLIT: Yes, absolutely, and I would ask the court reporter -- I offered that during the break. The court reporter can add up

whatever time I've used. You can have minute-for-minute increase to your time, but Rule 106 is not abuse, and I object strongly to that characterization.

MR. TSAI: Let's go off the record.

MR. STAMPFL: I would also like to say on behalf of Allergan defendants that I think this is improper, but plaintiffs have waived any right to object to this practice during the depositions of defendants' experts. Thank you.

VIDEOGRAPHER: Okay. We are now going off the record, and the time is 11:02 a.m.

(Off the record at 11:02 a.m.)

VIDEOGRAPHER: We are now going back on the record, and the time is 11:18 a.m.

QUESTIONS BY MR. TSAI:

Q. So you acknowledge in your report that there are patients with moderate to severe chronic pain and co-occurring

mental health disorders: Depression, anxiety, PTSD.

Do you recall that?

A. Yes.

Q. And co-occurring, co-occurrence, means these individuals have mental health disorders like depression or anxiety or PTSD while also having the disease of opioid use disorder?

A. Yes. Another way that -- because of the opioid epidemic, when we use the term "co-occurrence," we're often also using chronic pain as part of a co-occurring addict -- disorder with the disease of addiction.

Q. Have you done any analysis or have any other basis to quantify the percentage of people with opioid use disorder in Cuyahoga and Summit Counties who have co-occurring mental health disorders like depression, anxiety, PTSD?

A. I haven't done that analysis specific to Cuyahoga County. There are others who have done that analysis in other populations.

Q. Have you done any analysis or have any other basis to reliably rule out the likelihood that individuals in Cuyahoga and Summit Counties with opioid use disorder had mental health disorders prior to opioid use disorder?

MR. ARBITBLIT: Object to form.

THE WITNESS: No.

QUESTIONS BY MR. TSAI:

Q. If an individual who has a co-occurring mental health disorder, along with an opioid use disorder, along with chronic pain, commits suicide, let's say, how do you untangle and determine whether the suicide was due to the mental health disorder, the opioid use disorder or the pain?

MR. ARBITBLIT: Object to form. Incomplete hypothetical.

There's a question pending.

THE WITNESS: Yes, I'm sorry. I'm thinking.

MR. ARBITBLIT: Okay. Sorry.

THE WITNESS: No, that's okay.

So suicide and opioid use

disorder and chronic pain have a complex relationship in which each one can exacerbate -- each condition can exacerbate the other.

And the individual circumstances of the death would -- I would need the data on the individual circumstances of the death to be able to determine specifically -- well, to be able to try to assess to the best of my ability what was the reason for the death or what were the circumstances leading up to that death.

But -- I guess I'll just leave it at that time.

QUESTIONS BY MR. TSAI:

Q. And have you reviewed any information about, as you call it, the individual circumstances of any such deaths, the reason -- the context with respect to any opioid-related deaths in Cuyahoga and Summit Counties?

A. Well, I have reviewed the prescribing rates of opioids based off CDC

data in those counties, and I know that rates of prescribing are -- in a given county or in a given geographic region correlate with risk of opioid use disorder and opioid-related deaths in that reason -- in that region and are likely causative.

So in that sense I have reviewed some data.

MR. TSAI: I'll move to strike that answer.

QUESTIONS BY MR. TSAI:

Q. The aggregate prescribing rates of opioids, does that give you any information about the individual circumstances, to use your term, of any opioid-related deaths?

MR. ARBITBLIT: Object to form.

THE WITNESS: I do believe that the aggregate prescribing in that county is a risk factor for individuals living in that county as to whether they will die by overdose death.

QUESTIONS BY MR. TSAI:

Q. And do you agree that the

co-occurrence or the preexisting existence of mental health disorders such as depression, anxiety, PTSD, trauma, is also a risk factor for individuals as to whether they will die by opioid-related death?

A. It's not as important a risk factor as access to opioids as described by the Edlund study and decided in my report which finds that dose and duration of opioids is the most important risk factor and more important than individual factors such as co-occurring mental illness.

Q. You agree that the Edlund study described that individuals with a preexisting mental health disorder had higher rates of opioid use disorder than individuals with no mental health disorder?

Are you familiar with that -- you agree with that --

MR. ARBITBLIT: Objection.

QUESTIONS BY MR. TSAI:

Q. -- trend?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes.

QUESTIONS BY MR. TSAI:

Q. Okay. And similarly, individuals with two preexisting mental health disorders have higher rates of opioid use disorder than individuals with one mental health disorder; do you agree?

A. I haven't seen data on two versus one mental health disorder, so I --

Q. You didn't review that in the Edlund study?

A. Was it in the Edlund study?

Q. I believe so, but I'll move on.

A. Uh-huh.

Q. Have you conducted any analysis, quantitative analysis, or have any other basis to reliably rule out that the co-occurrence of the preexisting presence of depression, anxiety, trauma or other mental illness was an important contributing factor leading to opioid addiction and mortality in Cuyahoga and Summit Counties?

MR. ARBITBLIT: Object to form.

THE WITNESS: I feel like I already answered this question.

QUESTIONS BY MR. TSAI:

Q. So it should be quite easy for you to answer it.

Have you?

A. I think I did already answer it, just in terms of, on what basis.

Q. So am I right that your answer to this question is the aggregate prescribing rates, this is what you would point to?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. What does the aggregate prescribing rates have to do with the co-occurrence of mental illness?

A. I'm trying to figure out the question.

Could you rephrase the question?

Q. Do you have any basis to reliably rule out that the preexisting presence or the co-occurrence of mental illness among individuals in Cuyahoga and Summit County who had opioid use disorder, opioid use overdose, do you have -- have you done any analysis, do you have any basis to

rule out that mental illness was an important contributing factor to those outcomes?

MR. ARBITBLIT: Object to form.

THE WITNESS: So mental illness increases risk of addiction. Mental illness increases risk of having chronic pain. But the risk conferred by mental illness is not as great as the risk conferred by access to those drugs.

QUESTIONS BY MR. TSAI:

Q. And are you willing to offer the opinion to conclusively say that no individuals in Cuyahoga and Summit County with opioid use disorder or overdose had a mental illness co-occurring or preexisting?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. Would that be speculation on your part, or do you have a basis to make that opinion?

MR. ARBITBLIT: Object to form.

Misstates the testimony.

THE WITNESS: Could you rephrase the question, because you

used a double negative, so it's a little hard for me to track? I'm sorry.

QUESTIONS BY MR. TSAI:

Q. Well, is it your opinion that none of the individuals in Cuyahoga and Summit County who had opioid use disorder or an opioid use-related overdose had significant preexisting or co-occurring mental illness?

A. That is not my opinion.

Q. Okay. Do you agree that suicide rates are elevated, just isolating individuals with chronic pain, especially when there's a sense of hopelessness about treating that pain?

MR. ARBITBLIT: Object to form.

THE WITNESS: Sorry. I can't speak to the sense of hopelessness part, linking it to chronic pain. It is true that when people experience a sense of hopelessness, that can sometimes lead them to consider ending their lives. And it makes sense to me that individuals with chronic pain

would have elevated suicide rates, but I think the interplay between opioid therapy for pain, hopelessness, depression and suicide are complex because opioids themselves can contribute to depression and suicidality.

So it's very hard to tease apart what part of that is due to a separate depressive disorder and what part of that may actually be an opioid-induced depressive disorder.

QUESTIONS BY MR. TSAI:

Q. And what would you need to review and analyze to be able to tease apart those complex layers of confounding factors?

MR. ARBITBLIT: Object to form.

THE WITNESS: Those are hard to tease apart, even in clinical care.

Typically what we use is some kind of lifetime timeline to try to look at when the mood disorder began and when the opioids were started, but even that is not necessarily sufficient since opioids can worsen

mood.

QUESTIONS BY MR. TSAI:

Q. And we're talking about co-occurring mental illness. Let's talk about past history of substance use disorder.

Do you agree that past history of substance use disorder is a well-established risk factor for opioid use disorder?

A. Yes.

Q. And let me just give an example.

Edlund found that about half of opioid overdose deaths involved another drug, most commonly benzodiazepines.

Do you agree with that observation?

MR. ARBITBLIT: Object to form.

THE WITNESS: I agree that a large percentage of opioid overdose deaths involve another drug, commonly a sedative like a benzodiazepine.

QUESTIONS BY MR. TSAI:

Q. And can you give some examples of benzodiazepines?

A. Sure: Valium, Klonopin, Xanax, Ativan, Librium.

Q. And you talk about a large percentage of opioid-related overdoses involve an individual that, to put it bluntly, has another addictive substance in their system.

What do you mean by a large percentage? Can you be more specific?

A. Two-thirds of deaths involving a benzodiazepine also involve an opioid prescription.

Q. And if you could turn to your book, "Drug Dealer, MD," and page 146, the internal page number of your book, and the Bates number for that ends in 5680.

A. Uh-huh.

Q. It's the first full paragraph. It says, "Today, doctors' prescription for benzodiazepines continue to rise and are a major culprit in the epidemic of prescription overdose deaths plaguing this country. Nonetheless, benzodiazepines are relatively ignored in the national discussion on rising rates of addiction."

Is that still your belief?

A. Yes.

Q. And have you done any work or analysis to quantify to what extent benzodiazepines are, as you say, a major culprit in the epidemic of prescription overdose deaths plaguing this country?

A. So I published an article in the New England Journal of Medicine talking about the benzodiazepine problem. The article was not based on my own analysis, but was a review of published literature and some summative interpretations of how to intervene.

And based on other publications, we found a seven-time increased mortality involved benzodiazepines between late 1990s and 2016, two-thirds of which also involved an opioid.

Q. And did you, in connection with this article, dig into or quantify whether the benzodiazepine use occurred before or after the prescription opioid use?

A. No.

Q. So in your report on page 89,

you say, "Economic downturn and the E-flux of manufacturing jobs in towns across America in the last 30 years have contributed to so-called deaths of despair, early mortality in middle-aged, non-Hispanic whites due primarily to drug overdose."

Do you remember that passage?

A. What page?

Q. I believe it's page 89 of your report, Exhibit 1, subsection B, and you cite to the Case, Deaton study.

Do you recall that?

A. Yes.

MR. TSAI: So can we get Tab 18?

A. Oh, yeah. I found it.

(Lembke Exhibit 8 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. Okay. So if you could turn to -- the first page of the Case, Deaton article, this has a broad conclusion that "from 1999 to 2013, there was an increase in mortality among middle-aged, white, non-Hispanic Americans from all causes."

Is that right?

A. That's correct.

Q. And in the introduction, the bold introductory section, this Case, Deaton study concluded that "these increased mortality was due to various factors, including drug and alcohol poisonings, suicide, chronic liver disease and cirrhosis."

Is that right?

A. Yes.

Q. And second to the last -- just to be clear, do opioids cause deterioration or chronic liver disease or cirrhosis?

A. Not typically.

Q. Okay. And is it fair to say that those drivers of the increased mortality noted in the study were likely due to alcohol use disorder or alcoholism colloquially?

A. Yes.

Q. Okay. And in your report, you acknowledge and agree that, quote/unquote, "economic disadvantage is a contributing factor to opioid-related mortality risk."

Is that correct?

A. I would agree that it is one factor, but I also cited the Ruhm study, arguing that economic disadvantage contributes only 10 to 20 percent of mortality risk attributable to opioids, whereas the larger share of risk is due to the supply of opioids in a given geographic region.

Q. Okay. And have you conducted any quantitative analysis of your own to quantify the specific contribution of economic disadvantage to opioid-related mortality risk?

A. No.

Q. Do you have a model or an analytical framework to untangle any costs related to any such preexisting social and economic problems versus any conduct by any defendant with respect to Cuyahoga and Summit Counties?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that the Ruhm study could be used to inform a model with respect to the risk incurred by the supply of opioids

versus economic disadvantage.

QUESTIONS BY MR. TSAI:

Q. Have you in this case yourself done any work to rule out the likelihood that social and economic problems preexisting in the counties were an important contributing factor to observe opioid use disorder and mortality?

MR. ARBITBLIT: Object to form.

THE WITNESS: I have stated in my report that economic factors were a factor, but not the most important factor.

The most important factor is the supply of opioids in that county. That is my opinion.

QUESTIONS BY MR. TSAI:

Q. And your opinion regarding the relative degree of contribution of social and economic problems, economic disadvantage, versus any conduct by the defendants, is that based on grappling with any county-specific data, or is it only based on the Ruhm study that you cited?

MR. ARBITBLIT: Object to form.

THE WITNESS: It's based on my reading of the literature, not just this particular study, but also other studies showing that the amount of opioid prescribing in a given geographic region is the biggest predictor of opioid use disorder and opioid overdose in that region.

MR. TSAI: Okay. Can we do tab 27?

(Lembke Exhibit 9 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. So I would like to dig down into the actual ground floor circumstances of how folks get prescribed opioid medications.

So do you recall that last year you gave a live interview on KQED with Michael Krasny for a program entitled "Medical Community Divided on Medicare's Policy to Shorten High-Dose Opioid Prescriptions"?

A. Yes, I do.

Q. Okay. And the exhibit that we've just put in front of you, does this

appear to be a true and correct transcript of that interview that you participated in?

A. Yes, it does.

Q. Okay. And if you turn to page 8, they may have misspelled your name, but the Anna Lembke referred to, that's you?

A. Which page?

Q. It's page 8 of this exhibit.

A. Yes.

Q. Okay. So if you could turn to page 22 of the exhibit, and I'll start with line 2 of that page. I'll just read it.

You stated --

A. I'm sorry.

Q. Oh, sure.

A. I have two sets of page numbers here. Is this page 7, parentheses 22 to 25?

Q. That's correct.

A. Okay.

Q. And it's split up into quadrants. So it's the left-hand quadrant, page 22.

A. Yeah.

Q. And you stated, "While it's a very complicated connection that I do address

in my book, it's hard to kind of put it into a sound bite, but in general, you know, people who are suffering from poverty, unemployment, low education, are also people who are known to be at higher risk for addiction.

"It's also true that this is a population that has turn towards disability payments as a way to make ends meet, and in order to, you know, justify the sick role and get disability payments. Many of these individuals have been forced to take certain type of medications because taking a medication can legitimize the sick role. So it's a complex web."

Do you see that?

A. Yes, I do.

Q. What is "justifying the sick role"? What does that mean?

A. Well, that's a term that goes back to Talcott Parsons, who identified social roles that people adopt, and anybody who participates in the health care system and views themselves as a, quote/unquote, patient is someone who has adopted the sick

role.

Q. Okay. In your opinion -- is it still your opinion that certain individuals who have turned to disability payments are being forced to take certain types of medications to justify the sick role?

A. So this is part of -- this is an excerpt from, as I state here, a much more complicated issue that I address more thoroughly in my book regarding how disability can sometimes consciously or otherwise encourage people living in poverty to adopt the sick role as a way to get disability payments.

And in order to legitimize the sick role, they have to participate in that health care system, and in the '90s and early aughts and through today, it turns out participating in the health care system as a pain patient was actually dangerous because that -- the risk of being exposed unnecessarily to opioids was and continues to be very high, and exposure to opioids is one of the major risk factors for addiction.

Q. So you use the term "forced to

take certain types of medications." Who in your opinion is forcing these individuals to take opioid medications to justify what you've called the sick role?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. How does that mechanism work?

A. The individuals are being forced by economic circumstance.

Q. And this phenomenon of being forced by their individual economic circumstance to take certain medications to justify the sick role, have you reviewed any data specific to Cuyahoga or Summit Counties to determine whether that phenomenon occurred in the counties?

A. Nationally we've seen a huge increase in the number of people going on to disability for chronic pain conditions. For example, Social Security Disability insurance today, there are more than 8 million people enrolled in Social Security Disability insurance, primarily for chronic pain conditions.

So I believe that I can

extrapolate that to include Cuyahoga and Summit Counties, that there are individuals there who -- with chronic conditions who have gone on disability.

Q. Have you done the exercise of extrapolating specifically to Cuyahoga and Summit Counties?

A. Do you mean a quantitative analysis?

Q. Yes.

A. No.

Q. Is it your opinion that defendants have any role in structuring or implementing the Social Security Disability network?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think defendants have had a major role in the narrative around how chronic pain should be treated for patients who are participating in the health care system. And as a result, patients have been endangered because of being exposed to dangerous -- the dangerous substance that is opioids.

QUESTIONS BY MR. TSAI:

Q. Though, that's kind of confusing to me. The narrative is -- it's a very broad term.

A. Uh-huh.

Q. Can you point to any specific instance where any conduct by a defendant caused an individual within the disability payment network, for example, Social Security Disability, to have been forced to take their particular opioid medication?

MR. ARBITBLIT: Object to form.

THE WITNESS: So I think defendants have been involved in the change, the cultural change, in our conceptualization of pain and have created a climate in which doctors have been forced to treat pain with opioids, such that individuals who are on disability and get care for their chronic pain are at increased risk to be exposed to opioids.

QUESTIONS BY MR. TSAI:

Q. So you talked about climate, the culture and narrative.

These are all pretty qualitative, would you agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes.

QUESTIONS BY MR. TSAI:

Q. Can you point to a specific instance, act, that fits the scenario that you've outlined?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yeah.

So in my report, I talk about the Wisconsin Pain and Policy Study Group, and I provide evidence that the -- that industry funded the Pain & Policy Study Group, defendants funded the Pain & Policy Study Group, over a period of many years.

And the Pain & Policy Study Group, in turn, carried out programs that benefitted the industry, not only by increasing access to opioids and limiting regulatory scrutinary {sic}, but also changing the culture around pain treatment and identifying a model in which doctors feared retribution if

they didn't use opioids to treat pain.
QUESTIONS BY MR. TSAI:
Q. Can you point to any instance where anyone providing funds had a role in the design and conduct of the specific study or program that you're referring to?
MR. ARBITBLIT: Object to form.
THE WITNESS: On October 9, 2002, Joranson wrote to Mr. Kaiko, a Purdue representative, quote, "For the past several years, without your support, some of the progress reported below would not have been possible," end quote.
QUESTIONS BY MR. TSAI:
Q. And in your view is that designing and conducting the study?
MR. ARBITBLIT: Object to form.
THE WITNESS: It's not a study they're referring to. It's the model policy rolled out by the Pain & Policy Study Group, which had enormous influence in the way that pain was treated and is still treated today --

QUESTIONS BY MR. TSAI:
Q. So --
A. -- including creating a culture and a climate in which physicians felt required to use opioids to treat pain, and that if they were not using opioids, they were undertreating pain.
Q. Can you point to any instance where any person providing funding was involved in the preparation, review or approval of this model policy?
MR. ARBITBLIT: Object to form.
THE WITNESS: So there was a book that was published called "Responsible Opioid Prescribing," which listed as its funders Purdue Pharma, Endo, Janssen and Cephalon.
And that book was widely promoted and disseminated by the Pain & Policy Study Group, and then subsequently by the Federation of State Medical Boards and contributed to this change in culture.
QUESTIONS BY MR. TSAI:
Q. Okay. So it sounds like you're

going back to funding, but I'm asking about the specific content authoring, editing.
MR. ARBITBLIT: Object to form.
QUESTIONS BY MR. TSAI:
Q. Can you point to an example that shows that?
MR. ARBITBLIT: Object to form.
THE WITNESS: Can you repeat your question? I don't think I fully understand it.
QUESTIONS BY MR. TSAI:
Q. So you've said that the promotion was by PROP, correct?
MR. ARBITBLIT: Object. Misstates the record.
THE WITNESS: No.
QUESTIONS BY MR. TSAI:
Q. It was widely dissembled --
MR. ARBITBLIT: PROP was not in the question. It was EESG, Counsel.
THE WITNESS: Pain & Policy Study Group.
QUESTIONS BY MR. TSAI:
Q. Okay. That group. So I'm asking about the control, the authoring, the

editing of any specific content or analysis.
Other than funding, can you give me any example that supports your opinion about this culture or narrative or climate?
MR. ARBITBLIT: Object to form.
THE WITNESS: The funding is really what made it possible for the Pain & Policy Study Group to roll out this new paradigm around pain treatment.
They're not the only group that collaborated with the opioid pharmaceutical industry in this endeavor.
Also the Joint Commission was involved in that process, and they actually received content that was created by Purdue Pharma. That was then disseminated to hospitals who were trying to make Joint Commission accreditation. They used videos produced by Purdue. They used documents created by Purdue in order to change the paradigm around opioid

prescribing, including promoting opioid -- including promoting pain as the fifth vital sign.

There are also other examples in my report where consultants for the defendants were involved in research studies that were also misrepresentations of the evidence or used the evidence in a way that misrepresented the real science.

QUESTIONS BY MR. TSAI:

Q. And those are examples that you've set forth in your report?

A. Yes.

(Lembke Exhibit 10 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. Okay. Hand you next in order.

So do you recall that you gave a TEDx Talk in 2017?

A. Yes.

Q. And does the exhibit I've handed you appear to be a true and correct transcript of your TEDx Talk?

A. Yes.

MR. ARBITBLIT: Counsel, it's complete? Counsel, are you representing that it's a complete transcript or an excerpt?

MR. TSAI: This is a complete transcript. I know you're a big fan of completeness.

MR. ARBITBLIT: Yes, I am, and I'm not apologizing for it, so if you want to refrain from colloquy, please do.

QUESTIONS BY MR. TSAI:

Q. Is the "Dr. Lembke" referred to here you?

A. Yes.

Q. So if you could turn to page 3, and I'll start with line 4, and I'll read it.

"But the truth is that big pharma existed well before this public health crisis. And frankly the term 'quack' dates back to the 17th Century, so the question is: Why this drug and why now? To really be able to understand this problem, we have to recognize that this current opioid epidemic is a symptom of a faltering health care

system and a culture that has demonized pain."

Do you see that?

A. Yes, I do.

Q. And what do you mean when you say "to really be able to understand this problem, we have to recognize that this current opioid epidemic is a symptom of a faltering health care system and a culture that has demonized pain"?

A. What I mean is that the defendants have leveraged those problems in the delivery of health care today in order to meet their own agenda, which was a profit agenda.

So there are other factors that have contributed, but the primary factor is the role of the defendants in this case, and I would say that the defendants are additionally to blame because of their deliberate and for-profit misrepresentation of the evidence, whereas health care providers were unwitting accomplices.

Q. And presumably you would have stated that in this talk, outlining the major

contributing forces driving the opioid epidemic?

MR. ARBITBLIT: Object to form.

THE WITNESS: I had ten minutes in this TED Talk, and so I didn't cover everything that I believe or everything that's in my book.

QUESTIONS BY MR. TSAI:

Q. So because you had a limited time, just like we do here, you had to prioritize; is that right?

MR. ARBITBLIT: Object to form.

THE WITNESS: As I stated just above there in line 3, "Big pharma really is to blame."

QUESTIONS BY MR. TSAI:

Q. Well, you also state that, "In order to understand what caused this epidemic, we need to be aware of three invisible forces inside of the health care system that are driving this problem."

Do you see that?

A. Yes, I do.

MR. ARBITBLIT: Object to form. Argumentative.

QUESTIONS BY MR. TSAI:

Q. Is that -- those are your words?

A. Yes.

Q. Okay. Is that still your opinion?

A. Yes, but as I stated very clearly in my report, although there are other factors and other players in the opioid epidemic, the pharmaceutical opioid industry is the major driving factor and primarily responsible and basically took advantage of the other players as unwitting accomplices in their deliberate manipulation of the paradigm around pain treatment.

Q. Well, let's see what you said.

You enumerated the three forces that you say are driving this problem?

Do you see that? So can we go through those?

Is it your opinion still, as you stated in your talk in 2017, that the current opioid crisis is caused by, quote, "the industrialization of medicine or the Toyota-zation of medicine"?

MR. ARBITBLIT: Object to form. Misstates the record.

THE WITNESS: Yes, and I also mentioned that in my report, but again, importantly, the defendants basically took advantage of the fractured health care industry in order to misrepresent the evidence for their own gain.

QUESTIONS BY MR. TSAI:

Q. Well, can you tell the jury when you coined the term "Toyota-zation of medicine," or "industrialization of medicine," what do you have in mind by that?

What does that mean?

A. What I mean by that is the way in which doctors now no longer work in physician-owned practice. The majority of doctors now work for large, integrated health care centers, so they're essentially salaried employees, which means that they're required to practice medicine according to certain preordained protocols and algorithms.

They have much less autonomy than they've ever had before. There's

enormous pressure on them to make sure that patients are satisfied with their care, and all of that has -- there's also pressure on doctors to see patients more quickly, to get them in and out faster.

Q. All right. So --

A. And there's also pressures from the Joint Commission to meet certain quality measure standards.

So the bottom line is that doctors today have much less autonomy than they had previously and are required to practice medicine in ways mandated by, for example, Joint Commission quality measures.

Q. So they mandate to practice medicine according to certain preordained protocols and algorithms?

A. Yeah.

Q. Who is responsible for formulating those protocols and algorithms?

A. I believe that the defendants had a major and driving role in influencing those protocols in the treatment of pain.

Q. Do others have a role in implementing or formulating the protocols and

algorithms you refer to?

When a doctor -- say in your example, a doctor says, "Here's this preordained algorithm that's forcing me to practice in a certain way," where is he or she hearing that from?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. Where is it from?

MR. ARBITBLIT: Object to form.

THE WITNESS: They're hearing that from continuing medical education courses that, for example, I was mandated to attend in 2001 when legislation was passed in the state of California mandating every physician to attend a pain medicine course in order to maintain their license.

And at that course, I distinctly remember being taught many of the myths regarding opioid prescribing, information that's not based on science, about the benefits of the use of opioids and chronic pain and the low risk of addiction as long

as that individual has pain being prescribed opioids by a doctor. And we know none of that is true. That's just one of many examples, continuing medical education courses.

Another important example is the Joint Commission that accredits hospitals. They have an enormous influence on how we practice medicine today. We know as physicians that we have to meet Joint Commission standards, and the Joint Commission made assessing pain a quality measure in 2001 using material obtained by Purdue Pharma, that they then sold to hospitals, so that hospitals could meet Joint Commission requirements.

Doctors also get that information from the literature that they read, peer-reviewed articles, and many of those articles were misused essentially as promotional material with authors that were either consultants for pharma or with a study that was supported by pharma.

So those are the types of things I'm talking about.

QUESTIONS BY MR. TSAI:

Q. What about hospital administrators, do they have an important role in ordaining and mandating protocols and algorithms as you've referred to?

A. Hospital administrators have an important role in that, but, again, any role that they played, I believe, was as unwitting accomplices in the deliberate misrepresentation of the benefits of opioids and their risks by the defendants.

Q. Third-party payers, health insurance companies, they have an important role in ordaining the mandates and the protocols and the algorithms within the industrialized medicine system that you referred to?

A. Yes, they do.

Q. Okay. And when you say that, you know, there's a doctor, he or she feels enormous pressure to make -- satisfy his or her patients, get them quickly out, having industrial line, like an assembly line, who

is that pressure coming from?

MR. ARBITBLIT: Object to form.

THE WITNESS: That pressure comes from the patients themselves and the desire of the doctor to do a good job, and usually people who go into medicine are people who want to have quality relationships with their patients and feel like they help their patients. But there are also institutional pressures on doctors to have good doctor/patient satisfaction surveys.

And there's also importantly patients' expectations around what they expect the doctor will provide to them when they see that doctor.

And because of the defendants' actions, patients came to expect that when they had pain, they should get an opioid from their doctor. And we do know that there are data showing that when patients' expectations are not met, they're more likely to rate that doctor poorly.

So there was overall enormous pressure on doctors and on the system to prescribe opioids even for minor and chronic pain conditions in the absence of evidence because that evidence was misrepresented to all of these various parties by the defendants.

QUESTIONS BY MR. TSAI:

Q. Have you done any analysis -- do you have any other basis to reliably rule out the likelihood that there are these pressures on prescribing doctors following protocols and algorithms that came from sources that had nothing to do with defendants?

MR. ARBITBLIT: Object to form.

THE WITNESS: I have the lived experience. I got my degree in medicine in the early 1990s, and I lived through these, you know, past two and a half decades, and I personally felt the pressures from entities like the Joint Commission in order to practice in a certain way.

QUESTIONS BY MR. TSAI:

Q. And have you done any quantitative analysis to tease out, let's say, the role of hospital administrators, or the role of third-party payers, in any specific opioid prescribing decision of any doctor in Cuyahoga and Summit County?

MR. ARBITBLIT: Object to form.

THE WITNESS: No.

QUESTIONS BY MR. TSAI:

Q. So moving on, just briefly, you talked about the CME that you attended. It was back in 2001.

A. Yes.

Q. So after attending that CME, you didn't suddenly lose your independent medical judgment, right?

You still had your own independent medical judgment, you agree?

A. CME courses have an enormous influence on the information that doctors acquire on which to base their medical judgment.

So I didn't lose my medical judgment, but I can only make judgment based

on the information that I have and the misrepresentation at that CME and others like it across the country.

Q. And you invoke your personal experience?

A. Yes.

Q. So you didn't forget all of your prior medical education and training after leaving that -- how long was that session? One hour? Day long?

A. (Witness nods head.)

MR. ARBITBLIT: Objection.

QUESTIONS BY MR. TSAI:

Q. Did you forget your medical education and training?

MR. ARBITBLIT: Object to form.

THE WITNESS: Could you specify what medical education and training you're referring to?

QUESTIONS BY MR. TSAI:

Q. Yeah. Your medical school, your residency, your fellowship, all of your experience in the clinical setting, did the CME make you forget all of that?

MR. ARBITBLIT: Object to form.

THE WITNESS: I didn't forget it, but medicine is a discipline in which we must keep up with the science as it evolves, and a very busy clinician, including myself, does not have the time to read every single peer-reviewed article and dig into who funded it or whether or not they accurately represented their information.

So we rely on continuing medical education courses in order to acquire that knowledge. So when I went to that continuing medical education course, I acquired a body of knowledge that was not, in fact, based in the evidence, that then influenced my practice going forward and that of my colleagues.

QUESTIONS BY MR. TSAI:

Q. And to pick up on what you said, you have to keep up -- science evolves, medicine evolves.

So that's how medicine works, right? You have to make the best decisions

that you can based on the scientific evidence that's available --

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. -- at the time of prescription; do you agree with that?

MR. ARBITBLIT: Object to form.

THE WITNESS: As long as the science is being accurately represented.

QUESTIONS BY MR. TSAI:

Q. All right. So going back to your TED Talk, if you could turn to page 5 of that transcript?

A. Yeah.

Q. So starting on page 11, you say --

A. Page 5 or page 11?

Q. Sorry, starting on page -- line 11 of page 5, you say, "The second big invisible force driving this opioid epidemic is the medicalization of poverty."

Do you see that?

A. Yes.

Q. Is it your opinion now that a

big driver of the opioid epidemic is the medicalization of poverty as you stated here in 2017?

A. It's my opinion that the medicalization of poverty is a factor in the opioid epidemic, but not as big a factor as supply.

Q. Okay. And have you done any analysis to quantify the relative significance of the contributions of the factor of medicalization of poverty, to use your words, and prescription opioid supply?

MR. ARBITBLIT: Object to form.

THE WITNESS: I have not personally done that analysis, but there are others who I cite in my report who talk about, again, as I've answered in a previous question, economic factors not being the primary driver, and that supply of opioids in a given region being the primary driver of opioid use disorder and opioid overdose in that region.

QUESTIONS BY MR. TSAI:

Q. So at this time what percentage

or extent would you ascribe the contribution of medicalization of poverty to the opioid crisis?

MR. ARBITBLIT: Object to form.

THE WITNESS: It's hard for me to put a percentage on it. I would only say that the misrepresentation of the evidence has been the primary driver in the opioid epidemic.

In other words, the actions of the defendants have been the primary driver.

QUESTIONS BY MR. TSAI:

Q. Okay. But you can't say for any actual prescription of an opioid that the medicalization of poverty factor was not an important contributing factor to that decision?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. Is that right?

MR. ARBITBLIT: Object to form.

THE WITNESS: So can you rephrase?

I'm sorry, there's a lot of

double negatives, so it's hard for me to track.

QUESTIONS BY MR. TSAI:

Q. Let me put it this way. Can you reliably rule out the scenario that there were prescriptions, or even a lot of prescriptions, of opioid medications to residents of Cuyahoga and Summit Counties that were significantly influenced or driven, as you've used, by this phenomenon of medicalization of poverty?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would -- I can't reliably rule that out. I would say that that may be a factor for individuals in those counties, but it's not the primary driver.

MR. ARBITBLIT: Can we take a lunch break now? It's 12:15.

MR. TSAI: Sure.

VIDEOGRAPHER: Okay. We're now going off the record, and the time is 12:15.

(Off the record at 12:15 p.m.)

VIDEOGRAPHER: We are now going

back on the record, and the time is 12:53 p.m.

QUESTIONS BY MR. TSAI:

Q. Good afternoon.

A. Good afternoon.

Q. Just one background question. When were you retained in this case?

A. I was retained in January 2018.

Q. Do you agree that doctors are trained to use their independent medical judgment in making treatment or prescribing decisions for their individual patients?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that doctors today are -- the training around exercising their individual medical judgment is much less of an emphasis than it was, say, 30 or 40 years ago. I think there's much more emphasis now on practicing what's called evidence-based medicine. That's a social movement that began in the 1980s.

So there's enormous emphasis in

medical training now on basing your treatment decisions on what the evidence shows.

QUESTIONS BY MR. TSAI:

Q. In your opinion, do doctors have a duty, an obligation, professionally, to use their independent medical judgment in making decisions for treatment or prescribing based on their evaluation of their patients' medical condition?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think exercising independent medical judgment can be a good thing, if it's informed by quality evidence, but if independent decision-making is based on a misrepresentation of the evidence, that is a situation in which that independent judgment does not lead to good outcomes.

QUESTIONS BY MR. TSAI:

Q. Have you reviewed the product warning and labeling information for any of the defendants' products in this case?

A. Yes.

Q. Okay. So you would agree that the risks of addiction and overdose with respect to prescription opioids were clearly disclosed, right upfront, in a black box, front page, in bold letters for a doctor to see?

MR. ARBITBLIT: Object to form.

THE WITNESS: Are you talking about the black box warnings specifically, when you say "in a black box"?

QUESTIONS BY MR. TSAI:

Q. Yes.

Have you reviewed the black box opioid addiction and overdose warnings for defendants' prescription opioids?

A. Yes.

Q. And so you agree that a doctor practicing in Cuyahoga and Summit Counties would have to try not to see the black box warning about addiction and overdose risks to be unaware of it?

MR. ARBITBLIT: Object to form. Argumentative.

THE WITNESS: Maybe you could

rephrase the question.

QUESTIONS BY MR. TSAI:

Q. A doctor practicing in Cuyahoga and Summit Counties would have readily available in a black box on the front page of the product warning information the information warning about the risks of opioid addiction and abuse; do you agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would agree that the labeling -- that some of the labels at various points in time included warnings about addiction, but not the extent of the risk of addiction, which I think would be very important to include, especially given the false messaging on the part of defendants about the very low risk of addiction to opioids prescribed for a medical condition.

QUESTIONS BY MR. TSAI:

Q. In your opinion, were the warnings about the extent of risk of addiction in the product warning information that was approved by the US FDA inadequate?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that physicians were not adequately informed about the risks of addiction in prescribing of opioids.

To be adequately informed, simply knowing that there is a risk is insufficient. They would also need to know about the extent of the risk.

QUESTIONS BY MR. TSAI:

Q. Do you disagree with the FDA's approval of prescription opioid medications accompanied by those warnings?

MR. ARBITBLIT: Object to form.

THE WITNESS: So you're asking me -- I'm sorry, maybe you can rephrase the question, because I'm not fully understanding your question.

QUESTIONS BY MR. TSAI:

Q. Sure.

It sounds like you believe that the FDA-approved warning information that accompanied prescription opioids and were provided to doctors was inadequate.

Is that your opinion?

MR. ARBITBLIT: Object to form.
THE WITNESS: It's my opinion that to be fully informed about the risks of addiction to opioids, there should be included that -- the extent of the risk.
QUESTIONS BY MR. TSAI:
Q. And do you believe that the warning information that, in fact, accompanied prescription opioid medications made and sold by the defendants and approved by the FDA did not fully inform doctors of that?
MR. ARBITBLIT: Object to form.
THE WITNESS: So I have not been asked specifically to offer an opinion on the role of the FDA.
My understanding is that other experts will give testimony on that.
So my focus is not on that in my report.
QUESTIONS BY MR. TSAI:
Q. So you're not going to be offering an opinion at trial telling the jury that you think doctors weren't adequately

informed by the information that they received in the FDA-approved warning labels that accompany prescription opioid medications; is that correct?
MR. ARBITBLIT: Objection. Objection. Argumentative. Misstates the record.
THE WITNESS: Could you rephrase the question?
QUESTIONS BY MR. TSAI:
Q. You're not going to be offering an opinion at trial telling the jury that you think doctors weren't adequately informed by the information that they received in the FDA-approved warning labels that accompanied prescription opioid medications; is that correct?
MR. ARBITBLIT: Objection. Argumentative. Misstates the record.
THE WITNESS: Well, what I would be testifying to a jury is that there are many avenues by which physicians get information about the risks of a particular medicine that they're prescribing, that the FDA

warning label is one source of information, but there are many other sources, which I refer to in my report, including continuing medical education, peer-reviewed literature, quality measures put forward by the Joint Commission.
So the FDA labels are one part of that.
QUESTIONS BY MR. TSAI:
Q. Any other sources of information that doctors use in assessing the risks and benefits and the propriety of prescribing opioid medications?
A. Well, another unfortunate source is pharmaceutical company detailing, so representatives from the pharmaceutical industry going to doctors to essentially advertise their drug, which we know has an impact on prescribing, even when that doctor doesn't believe that they've been impacted by that contact.
So that's another source.
Q. You're familiar with the Cleveland Clinic?

A. Yes, I guess.
Q. In your opinion, do all the doctors at Cleveland Clinic who wrote prescriptions of opioid medications for their patients do so for the wrong reasons?
MR. ARBITBLIT: Object to form.
THE WITNESS: I would never make a broad, general claim like that.
QUESTIONS BY MR. TSAI:
Q. All right. Do you -- let's take a doctor at the Cleveland Clinic who wrote prescriptions for his or her patients for a defendant manufacturer who distributed opioid medication.
Have you -- do you have any reason to doubt that the doctor wrote it for good reasons?
MR. ARBITBLIT: Object to form.
THE WITNESS: What do you mean by "good reasons"?
QUESTIONS BY MR. TSAI:
Q. For a legitimate and appropriate and necessary medical condition.
MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. Have you reviewed any medical records or any other information that allows you to specify an instance where -- to doubt that a doctor wrote an opioid prescription for good reasons?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that doctors trained in the 1990s and early aughts continuing to today were misinformed about the benefits and risks of opioids such that there has been an enormous amount of prescribing opioids absent evidence to support their use, but not because those doctors are not good doctors.

In most cases they're well-educated and well-intentioned, but they have been led to believe something false about the benefits and risks of opioids such that their prescribing has led to the harm of their patients. And I venture to say that that includes doctors at the Cleveland Clinic.

QUESTIONS BY MR. TSAI:

Q. So let me give you a particular example.

Do you agree that the most common error made by physicians in using opioid analgesics for pain relief is failure to provide a sufficient dose to achieve optimal relief?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't agree with that.

QUESTIONS BY MR. TSAI:

Q. Okay. Tell me why you don't agree with that statement.

A. I think it's extremely difficult to determine what an optimal dose would be. There is no pain-o-meter, so we can't really objectively assess what a patient's pain is. The way that we use opioids to treat pain is very much based on what the prevailing practice is in a given institution, hospital, community, country, at that time.

And so I would argue that the most common error made by physicians in using

opioid analgesics for pain relief is the tendency to prescribe too high a dose and for too long a duration, and I think we have proof of that given that we are in the midst of an opioid epidemic, which is first and foremost an epidemic of overprescribing.

Q. So just to be clear, there's no thermometer analog, glucose meter analog, to actually measure how much someone is suffering from pain; you agree?

A. Yes.

Q. And because it's extremely difficult to determine what an optimal dose is, you would agree that the decision, with respect to dose of an opioid medication, is highly individualized?

MR. ARBITBLIT: Object to form.

THE WITNESS: No, I would disagree with that, because we have a wealth of evidence showing that opioids prescribed above a certain dose are highly dangerous and no reliable evidence showing efficacy used long term in the treatment of chronic pain.

QUESTIONS BY MR. TSAI:

Q. Do you agree that doctors at the Cleveland Clinic followed treatment and prescribing standards?

MR. ARBITBLIT: Object to form.

THE WITNESS: The standards for treatment and prescribing over the last three decades have been highly manipulated by the defendants, such that treatment standards today are not based on the evidence.

QUESTIONS BY MR. TSAI:

Q. Would you agree that the good doctors in Cuyahoga and Summit Counties and Cleveland Clinic know how to evaluate for themselves an article they read in a medical journal?

MR. ARBITBLIT: Object to form.

THE WITNESS: I believe that most doctors, including those in Cuyahoga and Summit County, don't have the time or the training to read peer-reviewed articles at the depth required to appreciate the information therein.

And furthermore, the articles -- many of the articles that they have been exposed to have been manipulated by the defendants and are a misrepresentation of the evidence, such that doctors in Summit and Cuyahoga County cannot use their good judgment in individual cases because they don't have accurate evidence to rely upon to inform that judgment.

QUESTIONS BY MR. TSAI:

Q. Would you agree that the good doctors at Cleveland Clinic and throughout Cuyahoga and Summit Counties know how to evaluate for themselves the information in an FDA-approved label?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would venture to guess that many doctors don't rely on the FDA label alone. It's not even a guess. Doctors do not rely on the FDA label alone in order to inform their decisions.

They're much more likely to be influenced by continuing medical

education courses they've attended, by the quality measures of their hospitals, and something as simple as how the practice of pain is conducted in that hospital.

QUESTIONS BY MR. TSAI:

Q. So am I hearing that your null hypothesis is that when a doctor, in any given locality, prescribes an opioid medication, then they have been duped into that decision?

A. Exactly, yes.

Q. And you've written and stated in various places that doctors themselves must bear some responsibility for the opioid epidemic, correct?

A. Yes.

Q. Okay. If a doctor in Cuyahoga and Summit Counties was prescribing opioid medications to residents of the county purely for their own personal profit, knowing that those individuals really didn't need the medicines for any medical pain condition, you would agree that doctor is violating medical ethics?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would agree that such a doctor is violating medical ethics, but I have also written and published on the problem of prescribing, and we have shown, using Medicare Part D data, that the increase in opioid prescribing in this country over the past three decades was not primarily due to a small subset of prolific prescribers or so-called pill mill doctors, unethical doctors, doctors who have lost their moral compass. Those types of doctors have always existed and will always exist.

In fact, the increase in opioid prescribing in this country has been primarily driven by all types of doctors across all types of specialties because of the major paradigm shift in the use of opioids for minor and chronic pain conditions as a result of misrepresentation of the evidence on the part of the

defendants.

QUESTIONS BY MR. TSAI:

Q. If a doctor in the counties was prescribing opioid medications purely for their personal profit, knowing that the individual they're providing opioids to did not have a legitimate pain condition, would you agree that doctor is committing a crime?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would agree that that doctor is committing a crime, but I think doctors like that constitute a small subset of the overall opioid prescriptions.

QUESTIONS BY MR. TSAI:

Q. Okay. Do you have a method of assigning the degree to which doctors in Cuyahoga and Summit Counties, in your words, bear some responsibility for the overprescribing of opioids for chronic pain versus the contribution of any of the other factors we've discussed today?

MR. ARBITBLIT: Object to form.

THE WITNESS: I believe that the majority of opioid prescribers in

Cuyahoga and Summit County and the rest of the country are well-intentioned doctors who were led to believe that opioids work for chronic pain and that the risks are low, including the risk of addiction and death.

QUESTIONS BY MR. TSAI:

Q. Have you reviewed any materials or have any other basis, or conducted any kind of quantitative analysis, to reliably rule out the likelihood that doctors in Cuyahoga and Summit Counties, in your words, bear some responsibility for the overprescribing of opioids for chronic pain to individuals in those counties?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that prescribers bear responsibility in the sense that they were misled by the defendants, and they weren't more questioning of what they were taught in the '90s and early aughts.

And so they bear some responsibility in the sense of not

having been more skeptical about the use of opioids, but in general, I believe that doctors were primarily duped by the defendants into prescribing opioids for chronic pain and minor pain conditions.

QUESTIONS BY MR. TSAI:

Q. And can you point to me anywhere where you have quantified the degree or extent of, as you say, the responsibility of prescribers in Cuyahoga and Summit Counties due to their lack of diligence or negligence?

MR. ARBITBLIT: Object to form.

THE WITNESS: It's not a lack of diligence or negligence. It's a matter of a paradigm shift in the way that doctors were pressured into treating pain with opioids, and I have quantified that in an article that we published in The Journal of the American Medical Association, showing that the increase in opioid prescribing based on the Medicare Part D database -- which is a database

that covers the entire United States, showing that increased prescribing has not been driven primarily by a small subset of prolific prescribers, but by a paradigm shift in prescribing opioids across all different types of prescribers such that we were all prescribing more opioids as a result of misrepresentation of the evidence by the defendants.

QUESTIONS BY MR. TSAI:

Q. And what was the quantification of the degree of responsibility for physicians in your analysis?

MR. ARBITBLIT: Object to form.

THE WITNESS: I feel like I've answered that question.

QUESTIONS BY MR. TSAI:

Q. Well, if there's an amount or a number, would that be in the article?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. Or was it a qualitative analysis?

A. It was a quantitative analysis.

The article uses the quantitative analysis of the Medicare Part D database to demonstrate that pill mill doctors, doctors who, as you suggested, are committing crimes are not the major factor. Those doctors exist.

Their behavior is reprehensible, but the vast majority of opioids prescribed in this country are prescribed not by such ethically compromised doctors, but by well-intentioned doctors who have been prescribing according to the misrepresentation of the evidence made available to them by the actions of the defendants.

(Lembke Exhibit 11 marked for identification.)

BY MR. TSAI:

Q. So I'll introduce exhibit next in order. So this is a --

A. I don't have it yet. Just grab it?

Q. I'll describe it to you while the court reporter is marking it.

I'll represent to you that this

is a press release from the US Department of Justice. It's dated August 22, 2018.

Were you aware of that press conference that happened right in Cleveland, Ohio?

A. I might have read about it if it was in the public domain. I don't specifically recall.

Q. Okay. So if you could turn to page -- starting on page 3 of this exhibit, press release, and I would just like to focus you in on this issue. It is the third paragraph from the bottom, and I'll just read it.

"My third announcement arises from Operation Darkness Falls, a joint operation against dark net fentanyl traffickers by the FBI, the IRS, our Postal Inspectors and Homeland Security investigators, again right here in northern Ohio.

"Today I'm announcing that this office has charged a husband and wife who, at the time of their arrest, were the most prolific dark fentanyl vendor in the United

States and the fourth most prolific on earth. They were known online as MH4Life.

"Last July, the Department of Justice seized Alpha Bay, which was the largest dark net marketplace in history."

Moving on to page 3. "This site hosted some 220,000 drugs and countless synthetic opioid overdoes, including the tragic deaths of a 13-year-old," and it goes on with a lot more details.

Are you familiar in your own clinical work with patients with opioid use disorder with individuals who are addicted to illegal or synthetic fentanyl?

MR. ARBITBLIT: Object to form. The question is unrelated to the preface.

THE WITNESS: So just to restate your question, you're asking me if I'm familiar in my clinical work with patients with opioid use disorder with individuals who are addicted to illegal or synthetic fentanyl?

QUESTIONS BY MR. TSAI:

Q. Have you worked with patients

who are addicted to illegal, synthetic fentanyl?

A. I have worked with patients who are addicted to illegal opioids.

Q. Okay. And we can agree that these dark net fentanyl dealers referred to in the Department of Justice announcement are criminals?

MR. ARBITBLIT: Object to form.

THE WITNESS: I'm not a lawyer, I haven't reviewed this, but it does sound like they are criminals.

QUESTIONS BY MR. TSAI:

Q. And if members of these dark net fentanyl and other illegal drug selling operation came into court and said, you know, "Based on Dr. Lembke's expert opinion, Gateway and Tsunami theories, I'm really not guilty of anything; it's really the legal drug manufacturers' and distributors' and pharmacies' fault," would you support that argument?

MR. ARBITBLIT: Object to form. Argumentative.

THE WITNESS: The individuals

being accused here are the dealers; is that right?

QUESTIONS BY MR. TSAI:

Q. They are the operators of these dark net fentanyl marketplaces.

A. Okay.

MR. ARBITBLIT: There's no question pending. That's a statement. Wait for a question.

THE WITNESS: Okay. Maybe you could rephrase your question.

QUESTIONS BY MR. TSAI:

Q. I'm just kind of seeing the bounds of your opinion.

So if these dark net fentanyl dealers said, "Well, you know, everyone has been duped by this climate that you referred to, I'm not guilty of anything, it's the legal prescription, supply companies' businesses" --

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. -- "that should be indicted," would you agree with that argument?

MR. ARBITBLIT: Object to form.

Argumentative.

THE WITNESS: No, and that's not the argument that I've made.

QUESTIONS BY MR. TSAI:

Q. So you agree that members of these dark net fentanyl and other illegal drug selling operations, including right here in northern Ohio, are responsible for their own criminal acts?

A. Yes.

Q. Okay. In other words, the existence of the legal prescription opioid medication business is not a defense to the crime of trafficking and possession of street heroin and other illegal opioids?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think without knowing more, it's difficult for me to comment, but most people who deal opioids are also themselves addicted to opioids. So if these individuals have become addicted to opioids, then that would be a mitigating factor in considering their punishment.

And I do think that the problem

more broadly of opioids, including illicit opioids, is directly linked to the problem of overprescribing medical opioids as evidenced by the graph showing that as opioid prescriptions have increased over the past 15 to 20 years, opioid overdose deaths have increased in lockstep.

QUESTIONS BY MR. TSAI:

Q. So you're not prepared to say that with respect to these illegal fentanyl operations that there is no connection to any defendants' conduct?

MR. ARBITBLIT: Object to form. Argumentative. Misstates the record.

THE WITNESS: I think that there's a potential for a connection to the defendants' conduct.

QUESTIONS BY MR. TSAI:

Q. Okay. Would you be speculating about that connection, or do you have any specific basis that any defendant played any part in these illegal fentanyl marketplaces?

MR. ARBITBLIT: Object to form. Argumentative and compound.

THE WITNESS: The connection to this conduct is a population of individuals who have become addicted to opioids as a result of the defendants' conduct, who are then seeking out illicit opioids as part of their addiction. That, to me, is a link.

QUESTIONS BY MR. TSAI:

Q. And you would support a defense, a mitigation defense, for these dark net fentanyl dealers based upon this idea?

MR. ARBITBLIT: Objection. Argumentative. Misstates the testimony.

THE WITNESS: I think you're -- maybe I'm misunderstanding you, but I think you're making a connection that I'm not making between the defense of these dark net dealers and the fact that we have an opioid epidemic.

Those, to me, are different things.

I don't know enough about the specifics of these dark net dealers to

weigh in on any kind of defense for them, but I do think that there is a link between the fact that they have a booming market for their illicit opioids and the fact that the defendants' conduct contributed to an opioid epidemic based on misrepresentation of the evidence that led to physicians who were duped overprescribing medical opioids.

QUESTIONS BY MR. TSAI:

Q. And the link that you posited, does that have any basis, anything specific to these individuals that are called out in this announcement?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, you are the one who asked me to speculate based on this, so I'm doing my best to try to answer your question based on very little information about these individuals.

QUESTIONS BY MR. TSAI:

Q. Okay. So other than this, you have not reviewed or are familiar with any

conduct in relation to these dark net fentanyl criminals; is that correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: I feel like I answered the question.

QUESTIONS BY MR. TSAI:

Q. In preparation for your book, you conducted interviews with patients who received opioids and prescribers of opioids, correct?

A. Yes.

Q. Okay.

MR. TSAI: Could we get Tab 29?

(Lembke Exhibit 12 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. So just to start out, in your report on page 80, you talked about manipulative behaviors of patients in attempting to obtain opioid drugs from their doctors.

Do you agree that patients themselves engage in manipulative behaviors to attempt to obtain opioid medications from their doctor?

A. Yes, but it's important to understand that behavior as part of the disease of addiction.

Q. Okay. What types of manipulative behaviors are examples that you're familiar with?

A. Doctors -- a patient's going to multiple prescribers to get the same or a similar prescription. Patients exaggerating their pain symptoms to get a certain type of prescription. Patients claiming to be allergic to a certain medication in order to get the specific medication that they want.

Those are some examples.

Q. Okay. So boiling it all down, in those instances that you've described, the patients are lying to their own doctors, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes.

QUESTIONS BY MR. TSAI:

Q. And in your opinion, do you believe that patients bear responsibility for their decisions to lie to their doctors?

MR. ARBITBLIT: Object to form.

THE WITNESS: To me, the lying is a result of their disease of addiction, so in some sense they do not actually have full capacity to be responsible for those actions because they're driven by the intense physiologic need to get more opioids.

QUESTIONS BY MR. TSAI:

Q. Have you reviewed any information or have any other basis to reliably rule out the likelihood that with respect to opioids, patients in Cuyahoga and Summit Counties lied to and manipulated their doctors?

A. I don't believe that Cuyahoga and Summit Counties are an exception to anywhere else in the United States. And that those individuals in Summit and Cuyahoga County who have become addicted to opioids may very well lie to and manipulate their doctors as part of their disease of addiction.

Q. So if you could turn to your Tab 29, and if you could go to the fourth page in that packet. Is that right?

Actually, yeah, if you could -- these are the handwritten notes that were provided by your counsel to us prior to this deposition. If you could -- and they weren't numbered.

If you could turn to what is sequentially page 9 of this packet, and if it would help, there's -- in the middle of that page, there is a heading or a phrase "how to fool doctors."

Do you see that?

A. Yes.

Q. So part of this is just a mechanical exercise to make sure I'm reading your handwriting.

Let me read it. "How to fool doctors: After the surgery it was easy to get, very patient. I would never try to push or inject what I was looking for unless it was the absolute thing to do. Easy on the -- for them, for the narcotics, treat him, get rid of him, seems like a nice guy, try to fool him as inconspicuously as you can."

Does that look about right?

A. Yes.

Q. Can you explain the context of the meaning of these notes?

A. Sure.

So this is a qualitative interview I did with a patient of mine who became addicted to opioids through a doctor's prescription, and he was somebody who was in recovery from alcohol use disorder for over a decade when he developed low back pain and was prescribed opioids for that low back pain.

That continued for some time, and he -- because of the phenomenon of cross-addiction, he immediately felt the same physiologic urges that he had had with alcohol but now replaced by opioids, and he continued to go to his doctor to ask for more opioids. He felt he was in pain, but he also felt on some level that he was craving opioids because of his addiction.

And then he -- when the doctor refused after a number of weeks to refill that prescription, he began going to a variety of walk-in clinics in order to get opioids from the doctors working there. And

he developed a kind of repertoire of behaviors that he used in order to get this prescription that he wanted. Namely, a prescription for opioids.

I will add that he is a very lovely man, and that because of his exposure to opioids through a medical prescription, he relapsed his addiction and engaged in these manipulative behaviors as a symptom of his addiction.

Q. So this individual for his particular case history, he had alcohol use disorder --

A. Yes.

Q. -- before ever being exposed to prescription opioids?

A. That's correct.

Q. Okay. And this individual, this is an example of someone who is lying to his doctor or multiple doctors in order to get opioids?

MR. ARBITBLIT: Object to form.

THE WITNESS: Yes. Uh-huh.

MR. TSAI: Can we go off the record?

VIDEOGRAPHER: Okay. We are now going off the record, and the time is 1:32 p.m.

(Off the record at 1:32 p.m.)

VIDEOGRAPHER: We are now going back on the record, and the time is 1:34 p.m.

QUESTIONS BY MR. TSAI:

Q. So staying on that page, if you could go down to the following paragraph. I just wanted to make sure I read this correctly in your notes. I have it as, "Some colleagues' goals is just to keep up percentage of money, just get them out the door, time and space, one trusted colleague said 'just give them what they want.'"

Did I read that accurately?

A. I'm sorry, where -- is that the same page or --

Q. Sorry. It is actually -- if you, in this packet, go to the -- do you see it near the end, this blue space?

A. The blue -- the first blue space?

Q. The last blue space.

A. The last blue space, okay.

And it is after the last blue space?

Q. It's before.

If you could flip four pages before that, please, and as a marker the top line says "fee structure."

MR. TSAI: Can we go off the record? Maybe it will just be easier for me to point it out.

VIDEOGRAPHER: We are going off the record. And the time is 1:35 p.m.

(Off the record.)

We're still on. Back on the record. It's 1:36 p.m.

QUESTIONS BY MR. TSAI:

Q. So on that page, the paragraph, I would say the second paragraph from the bottom, I'm going to read it to see if I have it accurately.

It says, "Some colleagues' goals is just to keep up percentage of money, just get them out the door, time and space. One trusted colleague 'just said give them what they want.'"

Did I read that accurately?
A. Not quite.
Q. Can you read it then?
A. Sure.
"Some colleagues' goals is just to keep the ED moving, just get them out the door, time and space."
Q. "One trusted colleague said 'just give them what they want'"?
A. Yes.
Q. And what does "the ED moving" refer to?
A. This is the emergency department.
Q. Okay. And generally, this packet of notes, you recognize this as a true and correct copy of your notes?
A. Yes, I do.
Q. Okay. And is this an example of medical practitioners, doctors, who feel pressured to, in your words, follow the assembly line of prescribing and treating patients?
A. Yes, it is.
MR. TSAI: I'm going to go off

the record. I would like to take a quick break. Thanks.
VIDEOGRAPHER: We're going off the record, and the time is 1:37 p.m.
(Off the record at 1:37 p.m.)
VIDEOGRAPHER: We are now going back on the record, and the time is 1:56 p.m.
(Lembke Exhibit 13 marked for identification.)
QUESTIONS BY MR. TSAI:
Q. So the next exhibit is Appendix I to your report, and it has five sections. Section B relates to Mallinckrodt. Can you turn to that?
A. Sure.
Q. So, first of all, have you reviewed any information that you can point to or have any other basis to say that any of the statements that you attribute to Mallinckrodt in Appendix I.B of your report were actually seen by any specific doctor or other person in Cuyahoga and Summit Counties?
A. I don't have specific examples, but I do believe these misrepresentations

were widely disseminated, including in Summit and Cuyahoga Counties.
Q. So are you speculating that they would be seen by doctors in Cuyahoga and Summit Counties but cannot point to any specific basis to back that up? Is that fair to say?
MR. ARBITBLIT: Object to form.
THE WITNESS: Because these misrepresentations were so deeply interwoven into medical education, it would be hard for me to believe that physicians in Summit and Cuyahoga Counties hadn't seen these misrepresentations, but I cannot point to any specific examples.
QUESTIONS BY MR. TSAI:
Q. And when you talked to doctors after your pair of talks last year in Ohio, did any of those doctors who practice in Cuyahoga and Summit Counties tell you that they relied on any of the statements that you attribute to Mallinckrodt specifically?
MR. ARBITBLIT: Object to form.
THE WITNESS: The doctors that

I spoke with validated that the misrepresentations laid out here in this section under Mallinckrodt were misrepresentations that they had been the recipients of in their medical training and that had led them to prescribe opioids in a way that they now realize was not evidence based.
QUESTIONS BY MR. TSAI:
Q. Did anyone use the word "Mallinckrodt"?
A. No, not that I recall.
Q. Did anyone use the word -- any of the products that are -- that Mallinckrodt made specifically?
A. Not that I recall.
Q. Okay. Have you done any analysis to determine whether or to what extent Mallinckrodt's marketing of opioid products, specifically Mallinckrodt, influenced prescribing decisions or rates in Cuyahoga and Summit Counties?
MR. ARBITBLIT: Object to form.
THE WITNESS: Mallinckrodt held the Train-the-Trainer events which

communicated these misrepresentations to individuals who then went throughout the country disseminating these misrepresentations, and I don't have any specific examples, but I wouldn't be surprised if they disseminated these misrepresentations also in Summit and Cuyahoga Counties.

Also Mallinckrodt promoted a book through the CARES Alliance called Defeat Chronic Pain Now!, and I wouldn't be surprised if that book was read by providers in Cuyahoga and Summit County and that book contained these misrepresentations.

QUESTIONS BY MR. TSAI:

Q. So you say you wouldn't be surprised, but can you point to anything in your materials that you've provided to us that specifically isolates the contribution of Mallinckrodt's conduct to promotional activity with respect to opioid prescribing or any adverse event in Cuyahoga and Summit County?

MR. ARBITBLIT: Object to form.

THE WITNESS: No, I cannot, but as I said before, I don't think Cuyahoga and Summit Counties are an exception to the national trend.

(Lembke Exhibit 14 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. So the next exhibit -- if you could turn to page 4 of the Mallinckrodt section.

A. Yes.

Q. So the topic under Number 5 is "Abuse-Deterrent Formulations Prevent Addiction," and you reference this exhibit, which is the next exhibit -- it starts MNK-T1. The range is 529004 to 529126.

And once that's introduced, I would like you to turn to the -- yeah.

If you could turn to the page that's -- has -- ends in Bates Number 9077.

A. 529077?

Q. 529077, correct.

Do you have any basis to say that Mallinckrodt ever characterized one of its own opioid products specifically as abuse

deterrent?

MR. ARBITBLIT: Object to form.

THE WITNESS: I believe that in one -- in the Mallinckrodt Train-the-Trainer events, there were speakers who claimed that abuse-deterrent formulations make abuse more difficult, and since Mallinckrodt sponsored that event, the implication is that that would include Mallinckrodt's products.

MR. TSAI: I'll move to strike.

QUESTIONS BY MR. TSAI:

Q. My question was: Can you name a particular product made by Mallinckrodt that Mallinckrodt characterized as being abuse deterrent?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. And if so, could you --

A. Broadly speaking, I would say that Mallinckrodt, like other defendants, misrepresented the risk of addiction to opioids prescribed for chronic pain, and in that sense communicated that the risk was low

or nonexistent, implying abuse deterrent.

MR. TSAI: And for the record, again, I'll move to strike, and that is absolutely not responsive to my question.

QUESTIONS BY MR. TSAI:

Q. Let me say it again. Can you name a particular product made or sold by Mallinckrodt that Mallinckrodt characterized as this product is abuse deterrent?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that Mallinckrodt and the other defendants in many ways characterized all of their opioids as abuse deterrent, as long as they were being prescribed by a doctor for a medical condition.

QUESTIONS BY MR. TSAI:

Q. Okay. And you cited this document, and you specifically cited in your report at page 529077, and this says, "Abuse-deterrent formulations, as the name implies, make the abuse of the medication more difficult. Recently the FDA released a guidance statement pertaining to the

evaluation and labeling of certain abuse-deterrent formulations."

That's what you cited in your report.

There's nothing here specific to a Mallinckrodt product; do you agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: I agree.

QUESTIONS BY MR. TSAI:

Q. If you could now go to -- back to Mallinckrodt section page 4 where we were, the Item 4, the topic is "Pseudoaddiction-Respond With More Opioids." I have it at 32.

So taking a step back, do you agree that if a patient came to you seeking a higher dose of opioid medications, for example, "Doctor, my spinal stenosis is killing me, I think I need more pain relief," would you automatically conclude that he has opioid use disorder, or would you further investigate?

MR. ARBITBLIT: Object to form. Incomplete hypothetical.

THE WITNESS: Your question suggests that there are only two

choices there, that either that's a legitimate reason to go up or he has opioid use disorder. I don't think that's how I would conceptualize that situation.

I think a patient could come in and say, "Doctor, I need more opioids because my pain is unbearable," and that that would not necessarily imply that that individual has opioid use disorder.

On the other hand, that also isn't indication to go up on the opioids since there's no reliable evidence that increasing the dose or even using opioids in the first place works for chronic pain and the risk factors go up with dose and duration.

(Lembke Exhibit 15 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. If we could look at the next exhibit. This is the document that you cited for this characterization.

And I would like to direct

you -- this is MNK-T1_1279950.

And it was produced in native, so I'll ask you to turn to the internal slide 45.

Do you see that?

Do you agree that on this slide that you cited in your report, it doesn't actually say "Pseudoaddiction-Respond With More Opioids," correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: You're referring to the heading? You're referring to my heading there?

QUESTIONS BY MR. TSAI:

Q. You referenced Slide Number 45?

A. Uh-huh.

Q. And you referenced that as a misrepresentation, which you characterize as "Pseudoaddiction-Respond With More Opioids."

Do you agree that what you referenced doesn't actually say that?

MR. ARBITBLIT: Object to form.

THE WITNESS: So that's a heading that "Pseudoaddiction-Respond With More Opioids," is in bold

letters. It's the heading to introduce the misrepresentation. That's not in quotes, so it's not an error.

QUESTIONS BY MR. TSAI:

Q. Do you have any basis to say that Mallinckrodt ever used the term "pseudoaddiction" in connection with one of its own products specifically?

MR. ARBITBLIT: Object to form.

THE WITNESS: This example here is from a Train-the-Trainer event that Mallinckrodt put on to educate a cadre of speakers who would again go out and disseminate the concept of pseudoaddiction more broadly among physicians in the United States. It doesn't matter that they didn't specifically mention their product.

They were promoting this misrepresentation, which changed the way that physicians prescribed opioids which promoted their product.

QUESTIONS BY MR. TSAI:

Q. Can you identify any

Mallinckrodt product that the company promoted using the term "pseudoaddiction"?

MR. ARBITBLIT: Object to form.

THE WITNESS: I feel like I answered that question.

QUESTIONS BY MR. TSAI:

Q. I haven't heard it, the name of a product; is that correct?

MR. ARBITBLIT: Object to form. Argumentative.

THE WITNESS: This reference here comes from something called Exalgo REMS and CARES Alliance Train-the-Trainer, CARES Alliance education module. So Exalgo, which is one of Mallinckrodt's products, is in the heading of this Train-the-Trainer event.

QUESTIONS BY MR. TSAI:

Q. Do you agree that there are indicators of addiction that are more indicative of addiction compared to others?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. As set forth in this slide?

MR. ARBITBLIT: Object to the form.

THE WITNESS: I believe that the diagnosis of addiction shouldn't be made on just one behavior. It has to be a 360-degree view of all of the circumstances involved.

QUESTIONS BY MR. TSAI:

Q. So stealing money to obtain drugs, you would agree, is a behavior more indicative of potential addiction than using more opioids than recommended?

MR. ARBITBLIT: Object to form.

THE WITNESS: Not necessarily. Given that individual's circumstance, stealing money to obtain drugs or using more than recommended, they may have equal severity of disease. It really depends.

Because of the myth perpetrated by the defendants that no dose is too high, I have seen many cases of patients who were receiving many more morphine milligram equivalents daily directly from their prescriber than

patients who are getting illicit opioids on the street.

So for several generations it wasn't necessary to go out and find a dealer or to steal money or any of these other listings in order to be severely addicted because you could get your opioids directly from a well-intentioned doctor who was taught that no dose is too high.

QUESTIONS BY MR. TSAI:

Q. So the differential diagnosis of whether a particular individual has true addiction under DSM-IV, DSM-V, what have you, versus needing more pain relief legitimately, does depend on individual circumstances, you would agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: I agree that all of the information needs to be taken into account with the caveat that several generations of physicians have been miseducated as to the evidence.

(Lembke Exhibit 16 marked for identification.)

QUESTIONS BY MR. TSAI:

Q. And you mentioned dose. If you could look at the next exhibit in order.

And this is still on page 4 of the Mallinckrodt section of Appendix I.B, Number 3 heading is the topic of "No Dose is Too High," and you cited MNK-T1_626241 through 626269, specifically at page 6262 and once the exhibit is marked, if you could turn to that.

A. What page number in the exhibit?

Q. 6262 is the ending.

A. It only goes up to -- oh.

Q. The next exhibit.

A. I see. I'm sorry. 626257?

Q. 626262.

A. Oh, okay.

Q. And once again, just for clarity, the heading that you have in your report, "No Dose is Too High," it doesn't actually say that in the page that you've cited in Mallinckrodt's document; do you agree?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't see those exact words, but equivalent words, quote, "Be sure to continue to titrate upwards until an effective dose is reached. This is essential to overall patient success," unquote.

QUESTIONS BY MR. TSAI:

Q. Do you have any basis to say that Mallinckrodt ever caused any doctor in Cuyahoga and Summit Counties to overtitrate to such a level that led to an adverse event?

MR. ARBITBLIT: Object to form.

THE WITNESS: I believe that doctors in the Summit and Cuyahoga County, like the rest of the nation, were taught that no dose is too high, such that they increased their doses of their patients with good intentions, putting those patients at imminent risk for overdose and addiction.

And we know that Cuyahoga and Summit Counties have not been spared the opioid epidemic, that there are if not equal, even worse rates of opioid

addiction and overdose in the state of Ohio and in those counties.

QUESTIONS BY MR. TSAI:

Q. Can you name a single specific doctor or patient that fits that scenario that you've just posited in Cuyahoga --

MR. ARBITBILT: Object to form.

QUESTIONS BY MR. TSAI:

Q. -- and Summit Counties?

MR. ARBITBLIT: Object to form.

THE WITNESS: I can't name specifics, but given the death rates...

QUESTIONS BY MR. TSAI:

Q. So in your report, you talk about an article that talks about a 1 percent rate of addiction.

Can you identify any instance where Mallinckrodt used the phrase "less than 1 percent get addicted"?

A. Mallinckrodt has used terms such as "rarely" and "uncommon" to describe the risk of addiction in patients treated with opioids for chronic pain.

I don't see the specific

reference to less than 1 percent, but they used equivalent phrases.

Q. And my last question: Do you have any basis to say that when doctors in Cuyahoga or Summit County heard the qualitative adjectives "low" or "rarely," that they had any specific number in mind?

MR. ARBITBLIT: Object to form.

THE WITNESS: The messaging that was dominant in the '90s and early aughts, all over the United States, was that the risk of addiction is rare, uncommon, less than 1 percent, very unlikely in patients treated with opioids for a chronic pain condition.

And so, hence, I believe that prescribers in Cuyahoga and Summit Counties were also led to believe that that was the case, even though that is a misrepresentation of the evidence.

QUESTIONS BY MR. TSAI:

Q. Did you conduct any survey or any analysis of any doctors in Cuyahoga and Summit Counties regarding what number they

associate, say, with the adjective "low"?

MR. ARBITBLIT: Object to form.

THE WITNESS: I didn't do a survey on the adjective "low" in Summit or Cuyahoga Counties.

MR. TSAI: Thank you. Reserving all rights, I'll pass the witness at this time. We should go off the record.

VIDEOGRAPHER: Okay. We're now going off the record, and the time is 2:20 p.m.

(Off the record at 2:20 p.m.)

VIDEOGRAPHER: We are now going back on the record, and the time is 2:22 p.m.

CROSS-EXAMINATION

QUESTIONS BY MR. LAVELLE:

Q. Good afternoon, Doctor. My name is John Lavelle, I'm an attorney at Morgan Lewis, and I'm representing Rite Aid of Maryland doing business as Mid Atlantic Distribution Center.

Are you aware that pharmacies have been sued as defendants in this

litigation?
A. Yes, I am.
Q. Okay. Now, when you were retained as an expert in the case in January of 2018, the pharmacies were not defendants; is that right?
A. I was not aware of that.
Q. Okay. When did you become aware that pharmacies were defendants in the litigation?
A. When I read the complaint.
Q. All right. You must have read the first amended complaint, because they weren't in the original complaint, right?
So when did you read the complaint that had the pharmacies as defendants?
A. About two weeks ago.
Q. Okay. In preparation for today's deposition.
A. That's right.
Q. So I'm going to be asking you some questions on behalf of a group of defendants who we refer to as the retail pharmacy defendants. So let me just name

them for you and ask you whether you're aware that they are defendants. So the first one is the client I am representing, Rite Aid.
You're aware that Rite Aid is a defendant in the case?
A. Yes.
Q. Other retail pharmacy defendants include Walgreens. Are you aware that they're a defendant in the case?
A. Yes.
Q. Are you aware that Walmart is a defendant in the litigation?
A. Yes.
Q. You're aware that CVS is a defendant in the litigation?
A. Yes.
Q. Are you aware that Giant Eagle is a defendant in the litigation?
A. Yes.
Q. Okay. And you became aware of all of those as defendants as of two weeks ago; is that right?
A. That's correct.
Q. Now, you prepared your report in this matter as of March 25, 2019; is that

right?
A. Yes.
Q. I'm just looking at the cover of your report, and that's the date that you have on it, right?
A. Well, I would say that my report is based on the research that I did prior to being retained by counsel, as well as the ongoing and additional research that I did beginning in the spring of 2019 until the finalized and submitted report.
Q. Understood.
So the finalized and submitted report was dated March 25, 2019; is that correct, Doctor?
A. I think that's the date, yes.
Q. Were you aware when you finalized this report that all those retail pharmacy defendants were defendants in the litigation?
A. I knew that pharmacies were defendants in the litigation, along with distributors and opioid manufacturers. I wasn't aware of the specific pharmacies that were named.

Q. All right. So I'm just trying to get the timing --
A. Yes.
Q. -- the timing right, because I think you said earlier, and I don't want to misrepresent it, but you learned about the specific pharmacies about two weeks ago when you were preparing for the deposition?
A. Yes. But I knew that pharmacies were named much earlier on.
Q. I see.
All right. So --
A. And I'm sorry.
Q. Yes.
A. I also read an earlier version of the complaint much earlier than two weeks ago. I can't remember the exact date that I read the earlier version of the complaint.
Q. Do you recall whether that earlier version of the complaint had pharmacies as defendants in the case?
A. I believe that it did.
Q. All right. Are you aware of what the plaintiffs' claims are against the retail pharmacies in this litigation?

A. I haven't been asked to express an opinion on that. I understand that there will be other expert witnesses who will testify in that regard, but broadly speaking, based on my understanding of the overall problem, as well as my reading of the complaint, pharmacies are accused of not acting or turning the other cheek when it was patently obvious that they were disseminating prescription opioid pain relievers to individuals who were struggling with opioid addiction and at risk because of opioids.

Q. So just to break that down. I'll have a couple follow-ups for you on that.

Do you know whether these retail pharmacy chains have been sued as distributors or as dispensers or both?

MR. ARBITBLIT: Object to form.

THE WITNESS: My understanding, based on what's in the public domain, as well as my reading of the complaint, is that there are essentially three groups of defendants: There are opioid

manufacturers; there are opioid distributors; and there are opioid pharmacies, some of which act also as dispensers.

QUESTIONS BY MR. LAVELLE:

Q. All right. So you believe, as you sit here today, that there are claims against the pharmacies as dispensers?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. LAVELLE:

Q. Is that what you believe?

A. Could you define "dispensers"?

Q. Yes.

Someone who fills prescriptions for a medical product such as an opioid.

A. Yes, that's my understanding.

Q. Okay. Now, I think you said in response to a question a couple moments ago that you have not formed any opinions with respect to the pharmacies; is that correct?

A. I was not asked to opine with respect to pharmacies, but broadly I agree with the complaint that all of those entities comprise what I have called the pharmaceutical opioid industry, and all bear

some responsibility.

Q. All right. So we're going to need to get into that in a little more detail because that was one question I had for you, is you used the term in this report "pharmaceutical opioid industry," but you haven't defined what that -- what you mean by that.

Can you explain what you mean by that and who was included in that?

A. The pharmaceutical opioid industry, as used in my report, refers to the named opioid manufacturers, the named opioid distributors, and the named opioid dispensing pharmacies.

Q. All right. Are you aware of any marketing of opioids that was done by any of the retail chain pharmacies?

A. No, I am not.

Q. And, in fact, you do not reference any marketing of opioids by any of the retail chain pharmacies in your report; isn't that correct?

A. That is correct.

Q. So when you have talked during

your deposition today and when you talk in your report about marketing by defendants or marketing by the pharmaceutical opioid industry, you're not referring to any of the retail chain pharmacies, right?

A. That's correct.

Q. You're not referring to Rite Aid; you're not referring to Walmart; you're not referring to CVS, Walgreens or Giant Eagle. Is that correct?

A. That's correct.

Q. Did you review any marketing materials from any of those entities?

A. I did not.

Q. To the best of your knowledge, did any of those entities actually engage in any marketing of opioids?

A. Not to my knowledge.

Q. Now, would you agree with me that pharmacists have a duty to fulfill prescriptions that are presented to them when there's a valid doctor-patient relationship?

MR. ARBITBLIT: Object to form.

THE WITNESS: Pharmacists have many duties, one of which includes

filling prescriptions, but they also have a duty to keep patients safe and when they see warning signs about a patient asking for certain types of medications, be it the type of medication or the mixing of that medication with another dangerous medication or the quantity of that medication, they have a duty to warn the patient and potentially also contact the provider and warn the provider.

And if it's on a large-enough scale, I would think that they would have a duty to also alert the distributors, the FDA, anybody else who's involved in making sure that patient stays safe vis-à-vis these medications.

QUESTIONS BY MR. LAVELLE:

Q. Now, you do not have that -- you have not expressed that opinion in your report; is that correct?

A. That's correct.

Q. You weren't asked to offer an

opinion on that; is that correct?

A. That's correct.

Q. And you don't have that opinion to a reasonable degree of medical certainty; is that correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, I have that opinion, and I'm pretty certain about it, but I wasn't asked to opine on it in my report.

QUESTIONS BY MR. LAVELLE:

Q. Okay. If you believe that doctors were duped into increasing opioid prescriptions, do you believe pharmacists were also duped?

A. I think it's possible that on an individual basis some pharmacists were also not aware of the dangers with opioids. It's possible.

Q. It's possible, but you're not certain?

A. That's right.

Mainly because I'm not as familiar with pharmacy training as I am with physician training.

Q. What knowledge do you have about pharmacy training?

A. I know that they have a certification -- they have schooling, a certification process, but I don't know a whole lot more than that.

Q. Okay. You're not a pharmacist?

A. No. And I haven't studied what pharmacists go through.

Q. And you wouldn't hold yourself out as having expertise with respect to pharmacy?

A. That's correct.

Q. A second here. Do you have any knowledge as we sit here today concerning the distribution activities of any of those retail pharmacy chains that I mentioned earlier?

A. I have some knowledge based on what's in the public domain about distribution activities more broadly of opioid pain pills, specifically the influx of very large amounts of opioid pain pills in small communities that could not possibly be justified based on the need for analgesia in

that community.

Q. Do you know, as you're sitting here today, whether any of the retail chain pharmacies I mentioned earlier actually distributed opioids?

A. I have not been asked to opine on that.

Q. And you don't know which opioids they distributed, if any; is that right?

A. That's right.

MR. LAVELLE: Okay. I'm going to stop there. Thank you, Doctor.

THE WITNESS: You're welcome.

VIDEOGRAPHER: Okay. We're now going off the record, and the time is 2:33 p.m.

(Off the record at 2:33 p.m.)

VIDEOGRAPHER: We are now going back on the record, and the time is 2:35 p.m.

CROSS-EXAMINATION

QUESTIONS BY MR. MOONEY:

Q. Good afternoon. My name is Matt Mooney. I am an attorney with the law

firm of Williams & Connolly.

You said you read the complaint -- the complaints in this case, at least two weeks ago, possibly before; is that right?

A. Yes.

Q. And I believe you said that you're aware of the role of distributors in this case; is that correct?

A. That's correct.

Q. Which distributors have been named as defendants in this litigation?

A. Cardinal, McKesson, AmerisourceBergen are the ones that I recall.

Q. Okay. Do you know if any other distributors were named as defendants in this litigation?

A. I can't recall.

Q. Prescription Supply, have you ever heard of that company?

A. No.

Q. Do you know if they're named as a defendant in this case?

A. I don't recall.

Q. How about a company called

Henry Schein, do you know if they're a defendant in this case?

A. I don't recall.

Q. Miami-Luken?

A. I don't recall.

Q. Anda?

A. I don't recall.

Q. Earlier today you said that you acknowledged the distributors' contribution to the opioid epidemic; is that right?

A. Yes.

Q. Okay. Are you prepared to offer an opinion in this litigation concerning the contribution of any distributor to the opioid epidemic?

A. It's my opinion -- it's my understanding that other expert witnesses will be offering testimony on distributors. I've not been asked to offer testimony on that.

Q. Okay. And so when you referenced the pharmaceutical opioid industry in your report, are distributor defendants included in that insofar as -- strike all that.

You mentioned the pharmaceutical opioid industry in your report, and you told Mr. Lavelle that as you define that term, it includes manufacturers, distributors and pharmacies; is that right?

A. That's right.

Q. When you reference misleading or false marketing material and attribute it to the pharmaceutical opioid industry in your report, are you referring to the distributors that have been named as defendants in this case?

A. No.

Q. And in preparing your report, did you consider any documents that were produced by a distributor that is named as a defendant in this case?

A. No.

Q. Do you have any training or expertise in supply chain management?

A. No.

Q. Do you have any training or expertise in the distribution of controlled substances?

A. No.

Q. Do you have any training or experience in suspicious order monitoring for controlled substances?

A. No.

Q. Do you have any training or expertise in a distributors' legal or regulatory responsibilities concerning the distribution of controlled substances?

A. No.

Q. Do you have your report in front of you?

A. I do.

Q. Okay. If you don't mind turning to page 82 of your report.

Are you there?

A. Yes.

Q. Okay. Do you see where you say, "In the case of prescription opioids, factors relevant to that epidemic have been addressed throughout this report and are summarized as follows."

Do you see where it says that in your report?

A. Yes.

Q. And then one of the bullets

below says, "An efficient distributor supply chain made prescription opioids available on a mass scale to large numbers of people in rural and remote settings expanding both the elicit and illicit drug market and sets this opioid epidemic apart from prior epidemics and other drug epidemics."

Did I read that correctly?

A. Yes.

Q. And that paragraph doesn't have a footnote identifying any documents that support that position; is that correct?

A. That's correct.

Q. Okay. Where else in your report did you address the fact that an efficient distributor supply chain made prescription opioids available in a mass scale?

A. That's the only place.

Q. Okay. And what do you mean by "an efficient distributor supply chain"?

A. By that I mean the fact that very easily large quantities of opioid pain pills could be disseminated all across the country, even in remote and rural regions,

putting those individuals at higher risk because access to addictive substances is one of the major risk factors for becoming addicted.

Q. Okay. And are you going to be offering an opinion in this litigation that an efficient distributor supply chain made prescription opioids available on a mass scale?

A. It's in my report, so I will be offering that opinion.

Q. Okay. And so what did you -- what documents did you rely upon to determine that an efficient distributor supply chain made prescription opioids available on a mass scale to large numbers of people, expanding both the elicit and illicit drug market?

A. I based that on the epidemiology of the opioid epidemic and the fact that unlike other drug crises in our history which typically have been isolated to specific geographical regions, what we see with the opioid epidemic is a dissemination across all states, all counties, and I attribute that to this efficient distributor

supply chain.

Q. Okay. Did you review any documents or any distribution data related to the distribution of opioids in forming your opinion?

A. No, but I did have access to what is in the public domain regarding that.

Q. And did you review that and consider it in forming your opinion in this report?

A. Yes.

Q. Okay. And is that -- what data did you rely on?

A. I relied on what I read in the public domain regarding, for example, small towns in rural West Virginia that received millions of prescriptions for a town of a thousand people. Those aren't exact numbers, but just to give a sense of the problem.

Q. So you didn't review any specific distribution data related to prescription opioids?

A. That's correct.

Q. Okay. Did you conduct any analysis of the distribution of opioids to

Summit or Cuyahoga County in order to form an opinion in this case?

A. No.

Q. And so other than what you have read in the public domain about the number of prescription pills -- opioid pills that have been distributed, have you relied on any other information to opine that an efficient distributor supply chain made prescription opioids available in a mass scale?

A. No.

Q. Another bullet on that page 83.

A. Yeah.

Q. And so this is, again, something that -- this is something that you write, "In the case of prescription opioids, factors relevant to that epidemic have been addressed throughout this report and are summarized as follows," this is another one of the bullets, correct?

And you wrote, "The problem of addiction more broadly in society and culture today does not negate the significant role of opioid manufacturers and distributors in causing this epidemic."

Did I read that correctly?
A. Yes.
Q. Okay. And I think I understood you earlier to say that you're not offering an opinion in this case about the conduct of any distributor that's been named as a defendant in this case; is that right?
A. Except for what's in my report.
Q. Okay. So what is your basis for determining that the opioid distributors played a role in causing the opioid epidemic?
A. The widespread nature of the opioid epidemic.
Q. And what do you mean by "the widespread nature of the opioid epidemic"?
A. The fact that every region in the country has been affected. The fact that the risk of opioid addiction and overdose death in a given county is directly correlated with the amount of prescribing in that county.
Q. Anything else?
A. No.
Q. And this paragraph -- or this bullet also doesn't have a footnote

identifying any documents on which you relied to support your opinion, correct?
A. That's correct.
Q. And you didn't consider any documents that were produced by the distributor defendants in reaching the opinion that you have in that bullet, correct?
A. That's correct.
Q. You haven't done any analysis of the distribution patterns of any distributor, defendant or not, to reach that opinion; is that correct?
A. That's correct.
Q. When you mentioned earlier that you spoke at Ohio State University, at least in April 2018 and February 2019; is that right?
A. Yes.
Q. Did you tell the audience that you had been retained by the plaintiffs in this litigation during your talk?
A. I did not inform the audience that in April 2018, but if memory serves, I believe I did in February 2019, although I'm

not 100 percent certain.
Q. Okay. Your report identifies information, marketing, that you believe was -- promoted misconceptions concerning opioids; is that correct?
A. Yes.
Q. And your report doesn't identify any marketing claims by any of the distributor defendants, does it?
A. No.
Q. Okay. Are you aware of any distributor defendant that has been named in this case as having made a false or misleading marketing claim regarding opioids?
A. I didn't review that material.
Q. Is it your opinion that the distributor defendants were aware that marketing material concerning the safety and efficacy of opioids contained misleading or false information?
A. My guess is they were probably aware, but I don't have anything specific to base that on.
Q. Okay. And so when you say your "guess is that they were probably aware,"

you're not relying on any expertise to say -- to reach that conclusion, correct?
A. Well, I mean, my expertise is my research of the opioid epidemic more broadly, and my -- I agree with the complaint that this was a kind of collusion or a synchronicity among all of the defendants.
Q. Have you reviewed any documents that have been produced in this case that show that there is collusion or a synchronicity between the defendants in this case?
A. I wasn't asked to review those documents. I have not reviewed those documents.
Q. So that's just your opinion?
A. Yes.
Q. But it's not based on anything you've seen or reviewed for the purposes of this case?
A. That's correct.
Q. Okay. You described that there was a paradigm shift in the prescribing of opioids; is that right?
A. Yes.

Q. And I understand that you believe that that paradigm shift was due to certain false or misleading statements that were made; is that right?

A. That's correct.

Q. Okay. Setting aside for a minute the reasons for the paradigm shift, do you agree that because of the paradigm shift it was a generally accepted medical practice to prescribe opioid medications for the treatment of chronic noncancer pain?

A. Yes.

Q. And for the treatment of acute pain?

A. I think for the treatment of acute pain, it was already an established practice. It was the transition to using opioids for minor pain conditions and using opioids in high doses long-term for chronic pain that was really the departure from past practice and also from the evidence.

Q. Other than documents that the distributor defendants produced in this litigation, did you review any materials and consider them in forming your report that in

order to reach the opinions that you purport to have regarding the efficient supply chain and the distributor -- the opioid -- distributors' role in causing an opioid epidemic?

MR. ARBITBLIT: Objection. Argumentative.

THE WITNESS: No.

QUESTIONS BY MR. MOONEY:

Q. Okay. And so other than the public reporting that you've seen about the number of pills, you don't have any other basis to opine that opioid distributors played a role in causing an opioid epidemic?

MR. ARBITBLIT: Object to form. Misstates the record.

THE WITNESS: Yeah, I was not asked to give an opinion on that. I understand that other experts will give an opinion on that.

QUESTIONS BY MR. MOONEY:

Q. Okay. So you aren't going to get -- you aren't going to state that opinion at trial then; is that right?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, if somebody asks me my opinion, I will state what's in my report.

QUESTIONS BY MR. MOONEY:

Q. Okay. And what will be the basis for the opinion other than the public reporting that you've identified?

A. And the information that I read in the complaint.

Q. Okay. And you understand that the allegations in a complaint are not necessarily proven as true until the evidence introduced at trial supports them; is that right?

A. Okay. Yes.

MR. MOONEY: Okay. Can we go off the record for a moment?

VIDEOGRAPHER: Okay. We're now going off the record, and the time is 2:51 p.m.

(Off the record at 2:51 p.m.)

VIDEOGRAPHER: We are now going back on the record, and the time is 3:03 p.m.

(Lembke Exhibit 17 marked for

identification.)

CROSS-EXAMINATION

QUESTIONS BY MR. EHSAN:

Q. Good afternoon, Dr. Lembke. My name is Houman Ehsan, and I represent the Janssen defendants in this litigation.

Doctor, do you know which prescription opioids, if any, Janssen manufactures or manufactured?

A. I'm sorry? I didn't hear that.

Q. Do you know -- sure.

Do you know which opioid medications Janssen manufactures or manufactured?

A. Opana ER and Percocet.

Q. Thank you, Doctor.

I've handed you what's been marked Exhibit 17 to your report, which is -- or Exhibit 17 to this deposition, which is Appendix I.C of your report, and it specifically reference Janssen's misleading messages; is that correct?

A. Yes.

Q. Focusing your attention on the bottom of the page, A 3, you note that there

is a document that describes how opioids improve function and quality of life, and you reference a particular Bates number that ends in 573.

Do you see that?

A. Yes.

Q. And is it your opinion, Doctor, that this was a misleading message that Janssen disseminated?

A. Yes.

(Lembke Exhibit 18 marked for identification.)

QUESTIONS BY MR. EHSAN:

Q. Doctor, I'm going to hand you what's going to be marked as Exhibit 18.

And, Doctor, please note that the Bates stamp on this document ends in 5 -- or ends in 809573, which is the same Bates stamp as what's referenced in Item 3, Exhibit 17, we just talked about.

Do you see that?

If you go back to the first page of Exhibit 17, the last item on that page --

A. Yes.

Q. -- is a document from 573 to 575, and that happens to be the same Bates range for this document; is that correct?

A. Yes.

Q. I just want to take -- bring your attention to the very top left-hand side of this document.

Do you see how it states, "Draft 7/16/02"?

A. Yes.

Q. At the time you reviewed this document, did you appreciate that it was a draft document?

A. I did not.

Q. Did you believe that this document was, in fact, disseminated to anyone in particular?

A. I'm not sure I knew for sure whether it had been disseminated.

Q. Sitting here today, Doctor, would you agree that you don't have a basis to opine to a reasonable degree of medical certainty that this document, labeled with a draft notation, was actually disseminated to any doctor in Cuyahoga or Summit County,

correct?

A. If it wasn't disseminated, period, then it wasn't likely disseminated to doctors in Cuyahoga and Summit Counties.

Q. Well, do you have an opinion as to whether or not a draft document would be disseminated to doctors in the community?

A. Well, just because it says "draft" on it isn't proof to me that it wasn't disseminated.

Q. Well, would you agree that you cannot opine to a reasonable degree of medical certainty that the document wasn't altered or changed or edited before it was disseminated, if it was, in fact, disseminated?

A. I can't speak to that.

What's salient to me, however, is that Janssen was reprimanded by the FDA for this document, and if it wasn't disseminated, it's likely that without reprimand it would have been disseminated because it's very similar to the types of messaging that were otherwise disseminated.

Q. Again, you cite a draft

document and you believed the FDA reprimanded Janssen for this draft document; is that correct?

MR. ARBITBLIT: Object to form. Misstates.

THE WITNESS: Yes, I do believe that the FDA reprimanded Janssen for this document.

(Lembke Exhibit 19 marked for identification.)

QUESTIONS BY MR. EHSAN:

Q. Thank you, Doctor. You can put that aside.

I want to hand you a two-part document. And we will be marking that as -- I believe that's 19.

And I apologize for the fact that it's a two-piecer, but it was produced natively, so the first page actually has the Bates stamp and the native document is printed behind.

I want to focus your attention on page 3 of Exhibit 17, which is your Exhibit 1.C.

Let me know when you're there.

A. Page 3 of my report?
Q. That's correct.
A. Okay.
Q. Let me know when you're there.
A. I'm there.
Q. The second bullet point on that page references speakers' notes from a Janssen sales training presentation site to Joranson 2000 that -- to state that "Investigators concluded that the trend of increasing medical use of opioid analgesics to treat pain does not appear to contribute to increases in health consequences of opioid abuse, period."
Did I read that correctly, Doctor?
A. The second bullet point on page 3? Yes, you did.
Q. And the reference you give or the Bates stamp reference you give for this document is JAN-MS-0032787, correct?
A. Yes.
Q. If you look at the first half of what's been handed to you as Exhibit 19, do you see that that document bears the same

Bates stamp, JAN-MS-0032787?
A. I'm not --
Q. You have to look at the bottom of this document.
A. Oh, I see.
Q. Because it was produced natively unfortunately it doesn't have Bate stamps on the actual document.
A. Yes.
Q. Okay. And I'll represent to you that the natively produced document is the second half of that Exhibit 19 that I've handed to you.
I just want to draw your attention to the first page of the document.
Do you see that this is, in fact, a Duragesic PowerPoint presentation?
A. Yes.
Q. And do you see at the bottom there's a little note "For PriCara training use only. Do not duplicate, modify, distribute or use this item when detailing."
Do you see that?
A. Yes.
Q. Do you understand what the term

"detailing" means?
A. I do.
Q. And what is your understanding of that term?
A. It's the phenomenon of representatives from pharmaceutical companies going to -- directly to prescribers to, quote/unquote, educate them about their drug.
Q. So when the statement of this document bears a stamp that you are not to duplicate, modify, distribute or use this item when detailing, would that suggest to you, Doctor, that it should not be -- should not have been used by pharmaceutical representatives in their interactions with physicians?
MR. ARBITBLIT: Object to form. Misleading.
THE WITNESS: I'm quite doubtful that that small print at the bottom of this page had a substantial impact on the messaging that representatives from Janssen used when they went to detail prescribers or other trainees of Janssen messaging.

The overall messaging is consistent what I have in my report that the benefits of opioids were overstated and the risks were understated, and this is an example of that.
MR. EHSAN: I'll move to strike as nonresponsive.
QUESTIONS BY MR. EHSAN:
Q. Doctor, my question was a little bit more simple so let me ask it again.
Do you believe or -- let me ask it this way.
Is it your opinion that this particular PowerPoint presentation and its contents are an example of how doctors were misled by pharmaceutical messaging and marketing?
MR. ARBITBLIT: Objection.
THE WITNESS: Yes.
MR. ARBITBLIT: Go ahead.
QUESTIONS BY MR. EHSAN:
Q. Doctor, if you could go back -- you can put that document aside, thank you.

If you can go back to Exhibit 17. Actually, Exhibit 1.C, which is part of your report.

A. Oh, correct.

Q. Going to page 2, do you see you have a Section B titled "Risk Understated" and below that you have point 1 which is states "Addiction/Abuse is rare/uncommon/less than 1 percent."

Do you see that?

A. Yes.

Q. Now, Doctor, would you agree that the risk of addiction abuse or misuse of an opioid varies from patient to patient?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would say that individual factors from patient to patient have some role in the risk of who will develop an opioid use problem while receiving opioids for the treatment of chronic pain, but that far and away the bigger risk factor is dose and duration of that opioid.

QUESTIONS BY MR. EHSAN:

Q. And you anticipated my next

question.

Dose and duration of which you are going to prescribe a medication for a patient impacts the risk for that particular patient of developing abuse or misuse of a medication, correct?

A. I'm sorry, could you restate the question?

Q. Sure.

The dose and duration for which the prescription is written also impacts the risk of abuse or addiction for the patient receiving that prescription, correct?

A. Yes.

Q. Obviously the dose and duration for which you're prescribing the opioid will vary from patient to patient, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: It will vary from patient to patient, but the general trend over the last three decades is high doses for long duration putting very large cohorts of patients at high risk.

QUESTIONS BY MR. EHSAN:

Q. So let me ask the question slightly differently, Doctor.

If a patient was to ask you without any additional further information, Dr. Lembke, "What is my risk of getting addicted to an opioid," could you answer that question without knowing something about the patient's background, history as well as why the prescription is being written, for how long and at what dose?

MR. ARBITBLIT: Objection. Compound. Incomplete hypothetical.

THE WITNESS: Yes, I believe I could answer that question.

QUESTIONS BY MR. EHSAN:

Q. And what would you answer that -- how would you answer that patient's question?

A. I would say to the patient that based on the most reliable evidence, the risk of becoming addicted to an opioid, even when prescribed for real pain in the course of medical treatment, is at the very least 1 in 10. So it's a very common risk and it may

even be much higher than that. Volz, et al., which I cite in my report, talks about risk being 8 to 12 percent for moderate to severe opioid use disorder, and as high as 25 percent by my reading of the Volz data. So about a quarter of patients are at risk for developing an opioid use disorder in the course of chronic pain treatment, which is undoubtedly a very high risk.

Q. Doctor, do you understand that individual risk of a side effect with a medication are a zero-one phenomenon?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't understand your question.

QUESTIONS BY MR. EHSAN:

Q. Sure.

The patient will either develop the side effect or won't develop the side effect, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: That's not been my medical experience that it's cut and dried like that.

Some patients will need more or

less exposure to develop a side effect. Some patients will have a side effect if they combine that medication with another medication. Some patients may develop a side effect if they develop a medical condition that then results in that medication leading to a side effect.

So it's not a --

QUESTIONS BY MR. EHSAN:

Q. So let me show you this question.

When I would consent a patient for surgery and if the patient asked me, "What's my chances of dying," even assuming that the chance of dying with a carotid endarterectomy is 3 percent for the institution, no one is going to die 3 percent, Doctor. They're either going to survive the surgery or they're not going to survive the surgery. That means 3 out of 100 may die. That's where the 3 percent comes from, but for an individual, you either will experience the side effect or you will not experience the side effect.

Would you agree with me on that?

MR. ARBITBLIT: Object to form.

THE WITNESS: To me the salient point is that patients actually be given informed consent before consenting to an intervention, whether it's surgery or prescribing opioids.

QUESTIONS BY MR. EHSAN:

Q. I understand, Doctor.

But have you ever met a patient who was 20 percent addicted to opioids?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't even really understand your question.

QUESTIONS BY MR. EHSAN:

Q. Well, your patients are either addicted, they carry a diagnosis of opioid use disorder, or they don't, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: That's incorrect. The DSM-V stipulates that opioid use disorder is, in fact, a spectrum disorder based on mild, moderate to severe symptoms. So

people can have varying degrees of severity of their addiction.

QUESTIONS BY MR. EHSAN:

Q. But they either have an opioid use disorder, mild, moderate or severe, or they don't have a diagnosis of opioid use disorder, would you agree with that?

A. I would not actually agree with that, because the diagnosis of opioid use disorder has become increasingly complex due to changes in the criteria from DSM-IV to DSM-V, and also given the last three decades of the problem of overprescribing opioids for chronic pain, there are many individuals who are addicted to opioids who have only ever taken them as prescribed disqualifying them from DSM-V criteria.

So it is a very complicated issue. It's not, you know, cut and dry.

Q. So do you have patients who you have simultaneously diagnosed as having opioid use disorder and not having opioid use disorder?

MR. ARBITBLIT: Objection. Argumentative. Misstates the

testimony.

THE WITNESS: I don't think that's what I said.

QUESTIONS BY MR. EHSAN:

Q. Okay. Doctor, how about before the DSM-V criteria for opioid use disorder, going to DSM-IV-TR where there was dependence and abuse, do you have patients who are simultaneously dependent and not dependent to opioids?

A. The way that the DSM-IV criteria were defined was slightly different from the way that they actually were used in real practice. Opioid abuse was primarily for individuals who developed consequences due to their opioid use, whether or not they were physiologically dependent, and you can be addicted without necessarily being dependent.

Opioid dependence was to characterize individuals who had had these physiologic changes as a result of regular use of the substance, in addition to other psychological factors.

So there was this dichotomized

definition. The way that it was commonly used in practice is that for milder cases of opioid use disorder, opioid addiction, people would often use the opioid abuse nomenclature. For more severe forms, they would use the opioid dependence nomenclature.

With the DSM-V, they encoded widespread recognition that opioid use disorder is a spectrum, not everybody is equally addicted, and some people have milder forms and some people have more significant forms, and based on the number of criteria they meet, we diagnose either a mild, moderate or severe opioid use disorder.

But I would say one of the most challenging aspects in real clinical time is the difference between people who meet DSM-V criteria for mild opioid use disorder and those who don't because of the new criteria and meet criterion instead for opioid dependence, and that can be a real hard judgment call.

MR. EHSAN: Thank you, Doctor. I move to strike as nonresponsive. Doctor, I didn't ask you about DSM-V,

but I appreciate that. But in the interest of time, I'm going to move on. Can I get this marked next?

(Lembke Exhibit 20 marked for identification.)

QUESTIONS BY MR. EHSAN:

Q. Doctor, I've handed you what's been marked as Exhibit 20. It is a package insert from Duragesic fentanyl transdermal system, and if you look at the very last page, it bears an electronic signature of Bob Rappaport, who I'll represent is from the FDA of 2/4/2005, which is the date that this label became effective.

You can see that at the very, very last page --

A. Oh, here, I see.

Q. -- there's an electronic signature.

Have you ever seen a package insert from Duragesic before?

A. Yes.

Q. If you go to the very front page of the document, are you aware of what a black box is?

A. Yes.

Q. What is your understanding of a black box?

MR. ARBITBLIT: Counsel, she's already answered that question with an earlier inquirer. I don't want to stop you, but --

MR. EHSAN: Okay.

MR. ARBITBLIT: -- if it's only going to be a minute, but we're not supposed to duplicate --

MR. EHSAN: That's okay.

MR. ARBITBLIT: -- during this part of the process.

QUESTIONS BY MR. EHSAN:

Q. I'll move on only to say, Doctor, could you read the first paragraph in the black box warning of Duragesic?

A. "Duragesic contains a high concentration of a potent Schedule II opioid agonist fentanyl. Schedule II opioid substances which include fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone have the highest potential for abuse and associated risk of

fatal overdose due to respiratory depression. Fentanyl can be abused and is subject to criminal diversion. The high content of fentanyl in the patches, Duragesic may be a particular target for abuse and diversion."

Q. Doctor, do you find that language to be false or misleading?

A. No.

Q. Do you think that a doctor reading that portion of the package insert for Duragesic in 2005 would adequately understand the risks of prescribing a fentanyl patch for a patient --

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. EHSAN:

Q. -- at least as it relates to abuse or criminal diversion?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think that a prescriber reading this may take away from it that these -- that Duragesic and other opioids have addictive potential, but would still not appreciate the extent to which a patient being treated with opioids for

pain could actually get addicted in the course of medical care because of the misleading messaging to prescribers communicated to them, as long as they were prescribing opioids for a medical condition, there was a very rare, uncommon or less than 1 percent risk of getting addicted to the opioid.

QUESTIONS BY MR. EHSAN:

Q. So is it your opinion, Doctor, that despite the language saying that these medications have the highest potential for abuse and associated risk of fatal overdoses due to respiratory depression, that a physician would nevertheless accept what a pharmaceutical representative may tell him or her about the risk of the medication?

MR. ARBITBLIT: Object to form.

THE WITNESS: The defendants were remarkably successful at convincing several generations of prescribers that the risk was so low, as long as they were prescribing for a medical condition, that independent of

this black box warning, they need not be concerned about that in their patients.

QUESTIONS BY MR. EHSAN:

Q. And you agree that the black box doesn't have anything about that this risk is only applicable if the patient is not taking it as prescribed, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: I didn't quite understand your question.

QUESTIONS BY MR. EHSAN:

Q. Sure.

The black box language you read didn't have any caveats about taking it as prescribed or not as prescribed, correct?

A. The black box warning doesn't address that particular issue.

Q. If you go back to Exhibit 17, which is your report, Doctor?

A. Uh-huh.

Q. You can put that aside.

Again, on page 2, you cite several documents that specify -- or at least go to the topic of the understated risk in

Janssen's materials.

Do you see those?

A. Yes.

Q. And several of those date back to 2001, which are the first two bullet points, for example, correct?

A. Yes.

Q. Now, would you agree with me that the science in 2001 was different than the science in 2019, as it relates to the risk of opioid medication?

MR. ARBITBLIT: Object to form.

THE WITNESS: Not at all.

QUESTIONS BY MR. EHSAN:

Q. So it was known within the scientific community that these medications had the -- had a risk of addiction and abuse that was the same in 2001 as it is today?

A. Well, that's a different question, whether or not it was broadly known what the science showed. It was certainly known that opioids are highly addictive dating back to the Civil War, but because -- I'm sorry, did you want to --

Q. No, go ahead.

A. Because of the misrepresentation of the evidence beginning in the early 1990s, doctors were miseducated on this point, but the evidence was not new.

Q. Well, when you go -- please go to page 3 of that same section -- in your report which is the end of that same section. You cite -- you have a comment section. You cite several studies, but all those studies are from -- all those studies are from 2008, 2004, 2004.

Do you see those?

A. So the 2008 is a Fishbain meta-analysis, which reviews studies of the risk of opioid addiction in the 1990s. Furthermore, there were -- there were other studies that Fishbain also reviewed in earlier 1992 meta-analysis showing that the risks of addiction were as much as 24 percent.

So it was well-known in terms of what the actual evidence showed.

Q. But you don't cite any -- you don't cite any publication that predates 2004 in your comment section; is that correct?

MR. ARBITBLIT: Object to form.
THE WITNESS: The comment section here is an augmentation of the actual report because I decided that to put all of these promotional statements in the body of the report would make it harder to read, but they're all a piece. And I do discuss in my report the many examples in the literature showing higher risks of addiction, well above the less than 1 percent, called rare, predating 2001, in fact, going back to the early 1990s.
QUESTIONS BY MR. EHSAN:
Q. Doctor, do you believe that the use of opioids in cancer pain management is appropriate?
MR. ARBITBLIT: Object to form.
THE WITNESS: What do you mean by "appropriate"?
QUESTIONS BY MR. EHSAN:
Q. Do you believe that opioids can be used effectively in the treatment of cancer pain?

MR. ARBITBLIT: Object to form.
Incomplete hypothetical.
THE WITNESS: It really would depend on how long they were used, for what purpose, the other circumstances involved.
QUESTIONS BY MR. EHSAN:
Q. Do you believe opioids are effective for the treatment of cancer pain?
MR. ARBITBLIT: Object to form.
THE WITNESS: I don't believe that there's reliable evidence to show efficacy of opioids for chronic pain, even including pain related to cancer pain.
QUESTIONS BY MR. EHSAN:
Q. Thank you, Doctor.
One last document.
(Lembke Exhibit 21 marked for identification.)
QUESTIONS BY MR. EHSAN:
Q. I'm going to hand you what's been marked as Exhibit -- sorry, I'm going to hand you what's been marked as Exhibit 21.
Doctor, this is -- I apologize.

This is -- the first page is just the providence of this particular document, but I will represent to you that -- that this is a screen capture from a Food and Drug Administration website, and if you can read the tiny, tiny print on the second page of the document itself, it says, "Page last updated in December of 2008." It is in very tiny print.
A. Yes, I can see that.
Q. And if you look at this particular document, this is really tiny -- I'm trying to -- one second. I apologize.
Under the heading "Misuse and Abuse," which is on the second page, the second paragraph, and again, I apologize for the tiny print, it states, "According to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds taken exactly as prescribed is safe, can manage pain effectively and rarely causes addiction."
Do you see that, Doctor?
A. I don't.
Q. Okay.

A. Oh, yes, I do, under "Misuse and Abuse."
Q. Yes.
A. Yeah.
Q. Now, do you agree with that statement from the FDA?
MR. ARBITBLIT: Which page are you looking at?
MR. EHSAN: The second -- it's 202, under the heading "Misuse and Abuse."
THE WITNESS: So --
MR. EHSAN: It's the second -- the second --
THE WITNESS: Yeah.
MR. EHSAN: -- I won't even call it a paragraph, but the second full thing.
THE WITNESS: So that statement does not specify whether they're talking about acute versus chronic pain. In the case of acute pain, I would agree with that statement. In the case of chronic pain, I would disagree with that statement.

QUESTIONS BY MR. EHSAN:

Q. And that statement itself doesn't clarify whether it's acute or chronic or which one it's in reference to, correct?

A. That's correct.

MR. EHSAN: Thank you for your time, Doctor.

THE WITNESS: You're very welcome.

MR. ARBITBLIT: Counsel, before we switch, I just want to point out one thing with the document that you introduced, which is Exhibit 19, I'm sure it wasn't intentional, but we have a version of that that has meta-data attached to it that was provided to the witness, and it did not appear on the version that you introduced as Exhibit 19, specifically the -- these notes that accompanied the PowerPoint, and we can provide a copy to you after the deposition.

You can choose to replace it or not, but the question doesn't match the exhibit unless you have those

notes with it.

MR. EHSAN: Oh, that's perfectly fine. My questions were not at all about the contents of the document, per se. It was about the draft language and the stamp. So if you want to swap it out with one that includes the speakers' notes, that's perfectly fine.

MR. ARBITBLIT: Fine. Thank you.

VIDEOGRAPHER: Okay. We're now going off the record, and the time is 3:33 p.m.

(Off the record at 3:33 p.m.)

VIDEOGRAPHER: We are now going back on the record, and the time is 3:35 p.m.

CROSS-EXAMINATION

QUESTIONS BY MR. TAM:

Q. Good afternoon, Doctor. My name is Jonathan Tam, and I represent Purdue.

Have you ever been detailed by a Purdue sales representative about OxyContin?

A. I don't recall specifically being detailed by Purdue about OxyContin, but I have been detailed by representatives in the past.

Q. Representatives of Purdue?

A. Representatives of pharmaceutical companies over the years.

Q. Have you been prescribed OxyContin?

A. Dating all the way back to the beginning of my medical career, I'm sure that I have, but I don't recall any specific situation where I prescribed it.

Q. So as you sit here today, you don't recall -- strike that. Let me ask that again.

Did you ever prescribe OxyContin because of anything that a Purdue sales representative said to you?

A. I don't recall a specific event, but the messaging from Purdue pervaded the entirety of my medical training and had a huge impact on the way that I and my colleagues prescribed throughout the '90s and early aughts, including the influence, the

enormous influence, on the Joint Commission and pain as a quality measure leading to all of us prescribing more opioids, including OxyContin.

Q. So your testimony is that you believe you have prescribed OxyContin because of Purdue's marketing?

MR. ARBITBLIT: Object to form. Misstates.

THE WITNESS: I believe that due to the misrepresentations of the benefits and risks of OxyContin, that I have prescribed OxyContin inappropriately at some point in my career due to that messaging, yes.

QUESTIONS BY MR. TAM:

Q. Do you know how many OxyContin prescriptions you wrote that you think were inappropriate?

A. I don't have a specific recollection of specific prescriptions. I'm referring to the broader trend in OxyContin prescribing, which is well-documented.

Q. Do you know whether any of those patients that you prescribed OxyContin

to became addicted to OxyContin?

A. I don't know of any patients to whom I prescribed OxyContin who became addicted, but I have treated many patients who have become addicted to OxyContin through the prescriptions of other health care providers.

Q. How many patients have you treated who were addicted to OxyContin?

A. It's hard for me to quantify that. I've been practicing medicine for more than 20 years. I see somewhere between 20 and 40 patients a week. About, I would say, three-quarters of those patients are addicted to opioids. That's based on my sense of it. I haven't gone back and specifically counted, and a large number have reported getting OxyContin, and I currently have patients who are addicted to OxyContin and struggling with that in my current practice.

Q. You said that around 75 percent of your patients are addicted to opioids generally.

Has that figure changed over time in the span of your career? Is it more?

Is it less?

A. It has changed over time. So in the early 1990s when I was first starting my career, I actually didn't know much about addiction. I didn't know how to screen or intervene for that problem, but I became aware of more and more of my patients who were presenting for treatment of their psychiatric disorders manifesting signs and symptoms of opioid addiction, many of whom -- most of whom got those opioids from a well-intended prescriber.

So I became curious about the problem in an effort to help my patients. I started to learn more about the problem of addiction, and eventually I became the go-to person in my department to help patients who had become addicted to opioids. And so a much larger percentage of my practice today consists of patients addicted to OxyContin and other opioids.

Honestly in the early aughts, it could have been also a large number, but I wasn't aware because I wasn't educated and had asked those questions, and I didn't

appreciate the risk involved because of the way that I was trained in large part due to the misrepresentation of the evidence.

Q. The patients you've treated who were addicted to OxyContin, did any of them die from an overdose of OxyContin?

A. I have had patients die of overdoses, and I believe that there was OxyContin involved, but I can't say for sure.

Q. So you can't say for sure that the overdose was from OxyContin, can you?

A. That's right.

Q. In the patients you treat who are addicted to OxyContin, do you know whether they were lawfully prescribed OxyContin by their doctors?

A. The vast majority of the patients that I treat who are addicted to opioids started out with a lawfully prescribed opioid prescribed by their doctor for pain.

Q. And is your answer the same with respect to OxyContin specifically, so for the patients who are addicted to OxyContin, is it the case that most of those

patients were prescribed OxyContin lawfully from their own doctor?

A. Yes.

Q. But some of your patients did receive OxyContin from some other source; is that correct?

A. Yes.

Q. And what are those other sources?

A. Other sources could include an illegal online source or a dealer or an acquaintance or a family member.

Q. Now, for the patients who were prescribed OxyContin lawfully by their doctors, do you know whether they took the OxyContin as directed by their doctors?

A. The majority of my patients who are addicted to opioids began with a lawful prescription and took the prescription opioid, including OxyContin, just as prescribed.

Q. But did some of those patients eventually take them in a way that was inconsistent with their doctor's directions?

MR. ARBITBLIT: Object to form.

THE WITNESS: So the natural progression of the disease of addiction is that patients will need more and more to get the same effect. Often that need was actually accommodated by the prescriber because we were taught that no dose is too high.

So I have seen patients who have developed addiction to OxyContin and other opioids manufactured by the defendants who only ever took their opioids as prescribed.

And I have seen patients who have started out taking their opioids as prescribed and ultimately began to misuse those opioids.

So I have seen the full range.

QUESTIONS BY MR. TAM:

Q. And for the patients who you've treated that were addicted to OxyContin, were they also addicted to other substances?

MR. ARBITBLIT: Object to form.

THE WITNESS: Very frequently these were individuals who had no

prior history of addiction, who were not addicted to other substances.

QUESTIONS BY MR. TAM:

Q. But there were still some patients that you treated who were addicted to OxyContin who were also addicted to other substances?

A. There were some patients.

Q. Can you quantify that or offer a percentage of your patient population for that?

A. I would say more of my -- of my patients addicted to opioids -- I would say approximately 80 percent of them took the opioid as lawfully prescribed for most of their opioid exposure.

Q. I appreciate that. My question was a little bit different.

Of the patients you've treated who were addicted to OxyContin, what percentage of those were also addicted to other substances?

A. I can't tell you the percentage specifically addicted to OxyContin.

In my work, that's not a major

focus. What we focus on is morphine milligram equivalent doses and duration and the aspects related to their disease of addiction.

So I can tell you that the majority, 80 percent of my patients, addicted to opioids began taking their opioids as lawfully prescribed for a medical condition and through most of their opioid exposure took their medications as prescribed for that medical condition. So there was not deviant or abhorrent behavior in the majority of my patients, except in some portion of them at the very end.

Q. Have you been able to treat your patients who were addicted to OxyContin?

A. Yes.

Q. And have you been able to treat them successfully?

A. Yes.

Q. Have you conducted any research or analysis to determine how many prescriptions for Purdue opioids were written in Cuyahoga or Summit County for higher doses because of Purdue's marketing?

MR. ARBITBLIT: Object to form.

THE WITNESS: I have analyzed and followed the CDC data, looking at the number of prescriptions in Cuyahoga and Summit Counties written per 100 persons, which does not break down by specific opioid.

QUESTIONS BY MR. TAM:

Q. Are you done?

A. (Witness nods head.)

Q. Okay. So respectfully, I don't think that answers my question.

Have you conducted any research or analysis to determine how many prescriptions for Purdue opioids were written in Cuyahoga or Summit County for higher doses because of Purdue's marketing?

MR. ARBITBLIT: Object to form.

THE WITNESS: Purdue's marketing was instrumental in the paradigm shift that I've described that led to minimizing the risks and misrepresenting the benefits that was at the heart of the change in pain management in this country.

So I would say that Purdue's marketing strategies had a huge impact on Summit and Cuyahoga Counties.

QUESTIONS BY MR. TAM:

Q. I appreciate that's your opinion, but please focus on my question.

Let me try it another way. Can you tell me or quantify the number of prescriptions for Purdue opioid medications that were written in Cuyahoga or Summit Counties for higher doses because of Purdue's marketing?

MR. ARBITBLIT: Objection. Argumentative. Asked and answered.

THE WITNESS: So the quadrupling of opioid prescribing that we've seen nationwide since the 1990s, including in Cuyahoga and Summit Counties and including OxyContin, is a direct result of the marketing of Purdue Pharma.

QUESTIONS BY MR. TAM:

Q. The quadrupling of opioid prescribing, but that's all opioids, correct?

A. Yes.

Q. And you attribute all of those opioid prescriptions to Purdue?

MR. ARBITBLIT: Object to form.

THE WITNESS: Purdue had a major role in changing the paradigm around pain treatment.

QUESTIONS BY MR. TAM:

Q. What's your methodology for determining that they played a, quote, "major role"?

A. My methodology is my personal experience having been the recipient of Purdue's marketing. My methodology is the research that I did for my book, the more than 400 articles that I've read here, my study of the way that Purdue Pharma deliberately manipulated the Joint Commission, the Federation of State Medical Boards, the Wisconsin Pain & Policy Group, in order to change opioid prescribing practices in this country.

Q. Now, you referenced a quadrupling of prescriptions.

Is it your testimony that all of those prescriptions were for higher doses?

MR. ARBITBLIT: Object to form.

THE WITNESS: How would you define higher doses? How are you defining them?

QUESTIONS BY MR. TAM:

Q. Well, your report refers to prescriptions being written in high doses, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: My report cites evidence showing that dose and duration directly impact the risk of overdose and opioid use disorder.

QUESTIONS BY MR. TAM:

Q. What would you consider a high dose of OxyContin?

A. I base it on morphine milligram equivalents consistent with the CDC guidelines, anything over 90 morphine milligram equivalents, but in my report I also qualify that patients can suffer morbidity and mortality even at lower doses.

Q. So in the quadrupling statistic that you gave to me, you can't differentiate which of those prescriptions were for high or

low doses, can you?

MR. ARBITBLIT: Object to form.

THE WITNESS: The point that I made with the quadrupling -- well, actually, let me look at my report.

So in my report I cite Paulozzi --

QUESTIONS BY MR. TAM:

Q. What page are you on?

A. I'm sorry, I'm on page 11.

"By 2005 long-term opioid therapy was being prescribed to an estimated 10 million US adults. The volume of prescribed opioid analgesics was 100 morphine milligram equivalents per person in 1997.

"In 2007, the morphine milligram equivalent per person had increased to almost 700 morphine milligram equivalents.

"And a very recent study found that the 2017 level of morphine milligram equivalents had declined from its peak to 543 morphine milligram equivalents, which remain well over five times higher than the prescribing rate in 1997."

So my answer is due to Purdue's

marketing and that of the other defendants, there was not just an increase in the number of prescriptions, but also a large increase in the number of prescriptions written for chronic therapy and the dose written to patients.

Q. But you can't give me a specific number of prescriptions of OxyContin in Cuyahoga or Summit County, can you?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't really think it's relevant, but I can't give you a specific number.

QUESTIONS BY MR. TAM:

Q. If you could turn to -- I think it's Exhibit 17, which is Appendix I.A -- I.A of your report, sorry. And I.A is the part about Purdue.

Are you with me, Doctor?

A. Yes. Appendix I.A, page 1.

Q. Yes.

So can we agree that all of the documents that you cite in here that you attribute to Purdue are all dated 2001 or earlier?

A. No. The first one is 1997.

Q. Let me just make sure you understand my question.

I said -- I asked, can we agree that all of the documents that you cite in here that you attribute to Purdue are all dated from 2001 or earlier, from before 2001?

A. Oh, let me take a look.

MR. ARBITBLIT: While she's looking at it, I just wanted to point out that Exhibit 17 did not include the complete appendices and we included Janssen, so your reference to Exhibit 17, I don't think that document the witness has been asked to review now has been marked as an exhibit.

MR. TAM: Thank you for that clarification.

Do you have a copy?

MR. ARBITBLIT: Other than it might be part of the Exhibit 1, the report, it's not --

THE WITNESS: Yes, we can agree they are all dated 2001 or earlier.

QUESTIONS BY MR. TAM:

Q. Thank you.

And to address counsel's clarification, I appreciate it, I did refer to Exhibit 17, which is just the Janssen portion of Appendix I, but for the record, Exhibit 13 is the entire Exhibit 1, which would include the section that has the Purdue statements.

MR. ARBITBLIT: Okay.

QUESTIONS BY MR. TAM:

Q. Did you review any documents that Purdue produced from 2002 or later?

A. I reviewed a lot of documents, and I didn't focus on the dates, so I'm not sure.

Q. Can you identify a doctor from Summit or Cuyahoga County who saw any of the documents that you cite in Appendix I.A?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would answer what I answered to a similar question that was asked prior, that the kind of misrepresentation that I describe in my report was widespread and Cuyahoga

and Summit Counties would not have been exempt from that. So I believe that the doctors in Cuyahoga and Summit Counties were exposed to this misrepresented evidence as a result of the defendants' marketing.

QUESTIONS BY MR. TAM:

Q. And I appreciate that's your opinion. I'm just trying to understand the bounds of it.

So you're not going to come into court at trial and identify any Summit County or Cuyahoga County doctor who you say saw any of these documents in Appendix I.A, are you?

A. Not unless you ask me to review some specific document.

Q. And as you sit here today, you're not aware of any specific Cuyahoga or Summit County doctor who saw any of the documents that you cite in Appendix A?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TAM:

Q. Right?

MR. ARBITBLIT: Sorry.

THE WITNESS: I'm not aware of a specific doctor, but I believe that doctors more broadly in Cuyahoga and Summit Counties have been exposed to these marketing messages, as we all were.

QUESTIONS BY MR. TAM:

Q. And you can't identify any doctor in Cuyahoga or Summit County who relied on any of the statements or the content in the documents cited in Appendix I.A when they prescribed a Purdue opioid medication to their patients, can you?

A. Again, I would say I can't cite a specific individual, but more broadly, all physicians in the last two-plus decades have been misled by these false marketing messages, and it has fundamentally changed the way that opioids have been prescribed.

Q. Now, some of the documents you cite in Appendix I.A are from third parties, not Purdue, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: Could you define third parties?

QUESTIONS BY MR. TAM:

Q. Sure, why don't we do it this way.

Can you turn to page 7 of Appendix I.A, and you see your section heading number 4?

A. Yes.

Q. And then the first bullet under there, you cite a CME course, right?

A. Uh-huh.

Q. And you note that this CME course was supported by an education grant from Purdue Pharma and distributed by familypractice.com.

Do you see that?

A. Yes, I do.

Q. So it's your understanding that Purdue provided a grant for this CME, right?

A. That's my understanding, yes.

Q. Have you seen any evidence that demonstrates that Purdue controlled or dictated the content of this specific CME course?

A. There is evidence that when a pharmaceutical company sponsors a continuing

medical education event, that the physicians who leave that -- after having participated in that CME are more likely to prescribe the drug produced by the pharmaceutical company that sponsored the CME event.

Q. My question was a little different.

Have you seen any evidence about this particular CME that demonstrates that Purdue controlled or dictated the content of the CME?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't really think that that's that relevant. I think that the reason that Purdue funds continuing medical education courses is precisely to promote the false messaging because they have found that that's a very effective strategy for doing that.

QUESTIONS BY MR. TAM:

Q. Doctor, I appreciate if you think it's irrelevant, but I'm entitled to ask my questions.

Can you point me any evidence

that demonstrates that Purdue controlled or dictated the content of this CME?

MR. ARBITBLIT: Object to form.

THE WITNESS: I'll refer you to page 19 of my report, in which I quote from an article by Van Zee called "The Promotion and Marketing of OxyContin, Commercial Triumph, Public Health Tragedy." Quote, "From 1996 to 2001, Purdue conducted more than 40 national pain management and speaker training conferences at resorts in Florida, Arizona and California. More than 5,000 physicians, pharmacists and nurses attended these all-expense paid symposia where they were recruited and trained for Purdue's national speaker bureau. It is well-documented that this type of pharmaceutical company symposium influences physicians' prescribing even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns."

QUESTIONS BY MR. TAM:

Q. Doctor, nothing that you just read from the Van Zee study says that by funding a program Purdue has controlled or dictated the content of that program, right?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would disagree, but that is the very reason that Purdue and the other defendants fund these CMEs, because the CMEs promote their messages, key opinion leaders who promote the use of their drugs are invited and sponsored as speakers at these CMEs. That's how the whole system works.

QUESTIONS BY MR. TAM:

Q. Are you going to be offering testimony about the intent of defendants when providing funding for CMEs?

MR. ARBITBLIT: Object to form.

THE WITNESS: It's not a matter of offering an opinion on the intent. It's a matter of looking at the whole system and recognizing the patterns of influence and the way in which Purdue

Pharma and other defendants covertly infiltrated physician education in order to promote their false messages.

QUESTIONS BY MR. TAM:

Q. So your opinion is that by providing funding, a pharmaceutical company -- strike that. Let me try it again.

Your opinion is that when a pharmaceutical company provides funding for a program, it is necessarily controlling and dictating the content of the program simply by virtue of providing the funding?

MR. ARBITBLIT: Object to form. Misstates the record.

THE WITNESS: I think you've misstated my words.

What I am saying, and it's my opinion, but it's also based in evidence, that when a pharmaceutical company funds a continuing medical education course, it has a direct impact on the way that physicians prescribe, such that they are more likely to prescribe the medication that is manufactured by that company.

QUESTIONS BY MR. TAM:

Q. Right.

But my questions aren't directed about -- at what physicians are likely to do after they attend a CME.

My question is about the content in the CME itself.

Are you with me, Doctor?

A. Yes.

Q. So are you familiar with what unrestricted grants are?

A. Yes.

Q. Have you ever received an unrestricted grant?

A. I have.

Q. So what's an unrestricted grant?

A. An unrestricted grant is a grant whereby an individual can use those funds for whatever they want, essentially.

Q. And when you receive an unrestricted grant --

A. By the way, let me -- just -- I'm sorry.

Q. No.

A. I just want to say I've not -- I've never received an unrestricted grant from a pharmaceutical company. I've received unrestricted grants from Stanford for educational material that I worked on.

Q. Okay. So you anticipated one of my questions.

But --

A. Sorry to interrupt.

Q. -- when you receive an unrestricted grant, that means that the sponsor, the one who provided you the money, does not control or dictate what you do with that money or how you conduct your research, right?

MR. ARBITBLIT: Object to form.

THE WITNESS: What I think your line of questioning is missing is the subtle forms of influence because of the relationship that occurs between the individual who receives the grant from the pharmaceutical company and what they then choose to emphasize in a continuing medical education course.

And there's good evidence in my

report about the way in which Purdue Pharma and other defendants enlisted key opinion leaders and promoted their careers and had them speak at continuing medical education courses.

QUESTIONS BY MR. TAM:

Q. When you receive an unrestricted grant, your work is done independent of the sponsor or the funder, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: There is an important difference between receiving unrestricted grant from the university or from a purely educational entity versus receiving an unrestricted grant from a pharmaceutical company that has a profit agenda. And there's lots of evidence to show that when physicians accept even small gifts from a pharmaceutical company, even in unrestricted form, that will affect their prescribing. And there's lots of evidence to show that. Wazana, et al., is one of the -- one of the many

articles showing that, and I do cite that in the report.

MR. TAM: Respectfully I'm going to move to strike that answer as nonresponsive.

QUESTIONS BY MR. TAM:

Q. When you receive an unrestricted grant, your work is done independent of the sponsor or funder, correct?

MR. ARBITBLIT: Object to form. Misstates.

THE WITNESS: When I receive an unrestricted grant, I would like to believe that my work is done independently, but I concede that there may be some influence based on the source of the funding because it's human nature to want to please and be in positive relationships to those people who give us money or other forms of, you know, financial wealth.

One thing that's clear is the way in which Purdue Pharma cultivated relationships with thought leaders in

pain medicine in order to influence prescribing, and I give many examples in my report from the Pain & Policy Study Group to the Joint Commission to the changes in the DSM-V.

MR. TAM: I'm going to move to strike that second paragraph in your answer as nonresponsive.

QUESTIONS BY MR. TAM:

Q. Doctor, you're being paid as an expert in this case, right?

A. Yes.

Q. Do you think you're influenced by plaintiffs' lawyers?

A. My opinions in my report were formed before I ever had contact with the plaintiffs' lawyers. I'm on the record publicly in my book and with my opinions in this. So I think that although we're all susceptible to influence, including myself, I think that I have not been influenced by the plaintiffs' lawyers in this case.

Q. What about other experts who, unlike you, have not published their opinions prior to becoming experts in this litigation?

MR. ARBITBLIT: Object to form. Speculative.

THE WITNESS: I would like to think they're not influenced either.

QUESTIONS BY MR. TAM:

Q. Have you reviewed any agreements between Purdue and the Pain & Policy Study Group?

A. Yes, I have.

Q. And did you see documents that made clear that the funding that Purdue was providing was in the form of an unrestricted grant?

MR. ARBITBLIT: Object to form.

THE WITNESS: I have reviewed documents that have showed numerous defendants providing funding to the Pain & Policy Study Group over many years, which I think had a direct impact on the false messaging that changed the practice of opioid prescribing in pain treatment.

MR. TAM: Respectfully move to strike as nonresponsive.

QUESTIONS BY MR. TAM:

Q. But can we agree that those were unrestricted grants between -- that were provided by Purdue to the Pain & Policy Studies Group?

MR. ARBITBLIT: Object to form.

THE WITNESS: I can't agree with that just because I don't -- didn't see anywhere where it said unrestricted grant. I believe you that it may be an unrestricted grant, but I didn't see the payments highlighted as restricted or unrestricted.

And as I've already stated, I don't think it would make a big difference whether or not they were restricted or unrestricted.

(Lembke Exhibit 22 marked for identification.)

QUESTIONS BY MR. TAM:

Q. Can we mark this document as the next exhibit, please? I am handing you what I've marked as Exhibit 22. All right.

Doctor, do you see that this is

a letter from the Pain & Policy Studies Group to Purdue?

A. Yes.

Q. And it's dated October 5, 2006?

A. Yes.

Q. Okay. So the second paragraph says, "The purpose of this letter is to confirm that this contribution is intended as a gift and that all parties agree to the general conditions concerning gifts to UW-Madison. The university defines a gift and funding provided for general or unrestricted support for research, public service, instruction, fellowship, traineeships or other activities."

Do you see that?

A. Yes, I do.

Q. And if you look later in the paragraph, the second to the last sentence, it says, "The donor may not restrict publication by the university of the results of the work resulting from the gift in any way."

Do you see that?

A. Yes.

Q. All right. So can we agree that this document says that at least the $50,000 being provided by Purdue is unrestricted?

A. Yes.

Q. And are you aware that Purdue provided the Joint Commission with unrestricted grants?

MR. ARBITBLIT: Object to form.

THE WITNESS: I guess I would like to see specific material on that. I'm aware that Purdue Pharma provided the Joint Commission with educational material they disseminated. I wouldn't be at all surprised if they also provided unrestricted grants, but I can't say that I recall specific unrestricted grants.

MR. TAM: Doctor, I think that's my time. So I will reserve our rights and subject to any questioning that your counsel may have, concede my time to -- or pass the time to the next counsel.

VIDEOGRAPHER: We are now going

off the record, and the time is 4:13 p.m.

(Off the record at 4:13 p.m.)

VIDEOGRAPHER: We're now going back on the record, and the time is 4:16 p.m.

(Lembke Exhibit 23 marked for identification.)

CROSS-EXAMINATION

QUESTIONS BY MR. STAMPFL:

Q. Good afternoon, Doctor. My name is Karl Stampfl, and I represent the Allergan defendants. I've marked your Materials Considered list as Exhibit 23.

Do you have it in front of you?

A. Yes.

Q. And is this the document where you listed the materials you considered in forming the opinions in your report?

A. Yes, it is.

Q. Could you turn to the page 33 of Exhibit 23?

Do you see there that beginning at Entry 425 you list what you call Bates-stamped documents?

A. Yes.
Q. That's where the documents that you considered that came from the defendants' files, among others, are listed, correct?
A. Yes.
Q. You listed five documents that were produced by my client, Allergan, correct?
A. Yes.
Q. Were you aware that Allergan produced hundreds of thousands of documents in this case?
A. Yes.
Q. How did you select these five documents to review out of those hundreds of thousands?
A. These documents were provided to me by counsel.
Q. Do you think it's fair to opine about Allergan's marketing conduct based on review of only five out of hundreds of thousands of documents?
MR. ARBITBLIT: Object to form.
THE WITNESS: I do think that it's fair, yes.

QUESTIONS BY MR. STAMPFL:
Q. You have no idea what were in the other hundreds of thousands of documents, right?
MR. ARBITBLIT: Object to form.
THE WITNESS: I think it's fair because for 20 years, I was the recipient as a practicing physician of this misleading marketing, so I have a pretty good idea of what that constitutes.
And in reading the documents that I did, I felt like the themes were pretty well-saturated, and I didn't feel the need to read additional documents.
QUESTIONS BY MR. STAMPFL:
Q. Can you identify any statement that you're aware of prior to this case from Allergan?
MR. ARBITBLIT: Object to form.
THE WITNESS: I believe that Allergan's statements are pieced with the other defendants, that this is overall the marketing messaging that

they participated in collectively to change the practice of opioid prescribing by misrepresenting the risks and benefits.
QUESTIONS BY MR. STAMPFL:
Q. But you're not basing that on anything beyond these five documents out of hundreds of thousands, right?
MR. ARBITBLIT: Object to form. Misstates.
THE WITNESS: I'm basing this on my experience as a physician, being trained in the climate that was affected by the defendants' actions regarding these misleading messages, as well as these specific documents that I reviewed from Allergan.
QUESTIONS BY MR. STAMPFL:
Q. Have you ever been detailed by an Allergan or Actavis sales representative about Kadian?
A. Not to my specific recollection.
Q. Do you know anyone who's ever been detailed by any Allergan or Actavis

sales representative about Kadian?
A. Not to my specific recollection.
Q. Prior to your involvement in this case, did you know that Allergan sold opioids?
A. Yes.
Q. What opioids?
A. Kadian, which is long-acting morphine sulfate, and then it's also my understanding that Allergan acquired Teva Pharmaceuticals.
Is that accurate?
Q. I can't testify, but I can represent to you that, no, that's not --
A. Okay.
Q. -- that's not accurate.
A. Okay.
Q. So let me ask you: Sitting here today, can you identify any other opioids that Allergan sold?
A. No.
Q. Do you recall mentioning Allergan or Actavis even once in your book "Drug Dealer, MD"?

A. No, but the emphasis of my book was not specific opioids. It was the problem of opioid -- opioids more generally and the misrepresentation of the evidence and the promoting of false messages more generally.

Q. Now, you said a little bit earlier that the opinions in your report you put out into the public in your book and in other public statements prior to your report.

Do you recall that testimony?

MR. ARBITBLIT: Objection.

Object to form. Misstates.

THE WITNESS: Could you clarify the question?

QUESTIONS BY MR. STAMPFL:

Q. Yeah.

Didn't you just testify in response to Purdue's counsel questioning that we can know that you hadn't been influenced by plaintiffs' lawyers because you had published your opinions prior to your putting out your report in this case.

Do you recall that testimony?

A. I recall that testimony, but I think it's -- if I said that, it's a

misstatement.

I had opinions based on my own research prior to being involved in this litigation.

Since being involved in this litigation, I've had the opportunity to evaluate many more documents, which has only served to augment my opinions and elaborate on them. I haven't changed my opinions. They've been strengthened by the opportunity to review additional documents.

Q. And the additional documents that you've reviewed that were produced by my client were five out of hundreds of thousands; is that right?

MR. ARBITBLIT: Object to form. Asked and answered. Argumentative.

THE WITNESS: I think I answered that.

QUESTIONS BY MR. STAMPFL:

Q. Is it correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: I reviewed these documents that are listed in the Bates-stamped documents.

QUESTIONS BY MR. STAMPFL:

Q. It's certainly fair to say, Doctor, that you didn't review many more documents produced by Allergan, right?

MR. ARBITBLIT: Object to form.

THE WITNESS: I didn't feel it was necessary.

QUESTIONS BY MR. STAMPFL:

Q. You just made assumptions about Allergan based on the fact that it was a defendant in this case, right?

MR. ARBITBLIT: Object to form. Argumentative. Misstates the record.

THE WITNESS: I don't believe I made assumptions. I based my assumptions on the documents that I reviewed, on my clinical experience, on my own research on the opioid epidemic.

QUESTIONS BY MR. STAMPFL:

Q. Can you point to any research that you did about Allergan or anything it did or said prior to your report?

MR. ARBITBLIT: Object to form.

THE WITNESS: So this appendix

lists specific misrepresentations of the evidence, which are consistent more broadly with the misrepresentations by other defendants, and which are, I believe, instrumental in leading to the opioid epidemic.

QUESTIONS BY MR. STAMPFL:

Q. We can agree, can't we, Doctor, that it wouldn't be fair to blame Allergan for anything that any other defendant did or said, right?

MR. ARBITBLIT: Object to form.

THE WITNESS: I wouldn't necessarily agree with that. I think that there was a way in which the defendants utilized the messaging in concert to advance their own agendas.

QUESTIONS BY MR. STAMPFL:

Q. You're aware, aren't you, that Allergan didn't acquire Kadian until December 2008, right?

A. I was not aware of that.

Q. You didn't consider that fact in formulating the opinions in your report?

A. No.

(Lembke Exhibit 24 marked for identification.)

QUESTIONS BY MR. STAMPFL:

Q. I'm going to mark an excerpt from plaintiffs' complaint as Exhibit 24.

And you reviewed plaintiffs' complaint you testified earlier, right, Dr. Lembke?

A. Yes.

Q. And could you look at paragraph 51 from the excerpt I just marked?

A. I'm sorry, is it numbered --

Q. Paragraph 51 is on page 16.

A. Yeah.

Q. Do you see here that plaintiffs' complaint states in the middle of paragraph 51, "In 2008, Actavis, Inc., now known as Allergan Finance, LLC, acquired the opioid, Kadian, through its subsidiary, Actavis Elizabeth, LLC, which had been the contract manufacturer of Kadian since 2005."

Do you see that?

A. Yes, I do.

Q. So do you agree then that

Allergan didn't acquire Kadian until December of 2008?

A. Yes.

Q. So you have no basis to claim that Allergan or Actavis caused any rise in prescriptions prior to 2009, right?

MR. ARBITBLIT: So just to interject, it calls for a legal conclusion. Objection.

QUESTIONS BY MR. STAMPFL:

Q. I'm glad to repeat the question for you.

A. Please, thanks.

Q. Do you have any reason to believe that Allergan or Actavis caused any rise in prescriptions in 2009 when it acquired Kadian?

MR. ARBITBLIT: Object -- same objection. Calls for a legal conclusion.

THE WITNESS: No.

QUESTIONS BY MR. STAMPFL:

Q. Do you have any basis to claim that Allergan or Actavis caused what you referred to as the epidemic of prescription

opioid use to the extent that epidemic occurred prior to 2009?

MR. ARBITBLIT: Same objection. Calls for a legal conclusion.

THE WITNESS: No.

QUESTIONS BY MR. STAMPFL:

Q. You have no basis to claim that Allergan or Actavis caused the opioid crisis to the extent it occurred prior to 2009, correct?

MR. ARBITBLIT: Calls for a legal conclusion.

THE WITNESS: Correct.

QUESTIONS BY MR. STAMPFL:

Q. In fact, isn't it true that by 2010, shortly after what was then known as Actavis acquired Kadian, opioid prescriptions had begun decreasing?

A. Opioid prescriptions began decreasing around 2012, so there was quite a bit of time between 2009, when Actavis acquired Kadian, and 2012.

Q. Could you look at paragraph 14 C of your report, please?

Do you have your report in

front of you, Doctor?

A. I do.

MR. ARBITBLIT: Do you have a page number?

MR. STAMPFL: I don't. It's paragraph 14 C. I'll try to get one for you. I believe it's page 87.

QUESTIONS BY MR. STAMPFL:

Q. Now, I know you just said 2012, but do you see that here in paragraph 14 C, second sentence, you write, "Opioid prescriptions per person in the total US increased annually at an average rate of 6.9 percent per year until 2010 and decreased at an average rate of 3.8 percent per year from 2010 until -- or through 2015."

Do you see that, Doctor?

A. Uh-huh.

Q. Do you agree that by 2010, shortly after Actavis acquired Kadian, opioid prescriptions began, in fact, decreasing?

A. Well, this is opioid prescriptions per person, so there are multiple ways to measure this.

Q. Okay. In that case, I'll

withdraw my question and revise it.

Do you agree that by 2010, shortly after Actavis acquired Kadian, opioid prescriptions per person had begun decreasing?

A. Yes.

Q. Do you agree that by 2010, shortly after Actavis acquired Kadian, MME per person had begun decreasing?

And the reference is the next sentence, 14 C.

A. Yes.

Q. Would the opioid crisis have occurred had Actavis never purchased and promoted Kadian?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think the opioid crisis would have occurred had -- independent of that.

QUESTIONS BY MR. STAMPFL:

Q. Isn't it fair to say, Doctor, that Allergan didn't cause the opioid crisis?

MR. ARBITBLIT: Object to form.

THE WITNESS: I believe that all of the defendants played some

role, but based on this timeline, it does appear that Allergan's role may be less.

QUESTIONS BY MR. STAMPFL:

Q. Don't you think to the extent that Allergan had any role in the opioid crisis, it was very limited?

MR. ARBITBLIT: Object to form.

THE WITNESS: I actually believe that the opioid crisis continues to this day, and that these misrepresentations continue to be a problem. And so to the extent that Allergan is contributing to that problem, Allergan has responsibility.

QUESTIONS BY MR. STAMPFL:

Q. I understand.

So when was the last time Allergan promoted Kadian in any way?

And, Doctor, are you referring now to Appendix I.E?

A. Yes, I am.

Q. And I'll represent to you that the latest date you have in there is February 2013.

Does that sound right to you?

A. Yes, it does.

Q. Can you identify any allegedly inappropriate Allergan statements after February 2013?

A. I would have to re-review the documents, specifically paying attention to dates, which is not something that I paid attention to.

Q. And the documents that you would have to re-review are the five documents that you considered about Allergan, correct?

A. Yes.

Q. Were you aware that in Appendix I.E you, in fact, relied on documents that weren't marketing or even training materials from Allergan but rather Kadian's prior owner, Alpharma?

A. I wasn't aware of that because they were Bates stamped or -- Allergan.

Q. You understand that the Bate stamp just means who produces the document, not who used or created the document, right?

A. Yes.

Q. So do you have any basis to try to hold Allergan responsible for anything that the prior, unaffiliated owner of Kadian did or said?

MR. ARBITBLIT: Objection. Argumentative. And calls for a legal conclusion.

THE WITNESS: Well, it doesn't matter so much who produced the document. It's whether or not Allergan used the document.

QUESTIONS BY MR. STAMPFL:

Q. Precisely, that's right.

So if it's a document that another company used, we couldn't blame Allergan for that document, right?

MR. ARBITBLIT: Objection. Argumentative. Calls for a legal conclusion.

THE WITNESS: So Kadian marketing overview with sales representative training in October of 2011, after Allergan acquired Kadian.

QUESTIONS BY MR. STAMPFL:

Q. Okay. Can you look at the bottom of page 2 and top of page 3 in your Appendix I?

Do you see that you're referring to something called the Kadian Learning System?

A. Uh-huh.

(Lembke Exhibit 25 marked for identification.)

QUESTIONS BY MR. STAMPFL:

Q. And I'm going to mark that document now as Exhibit 25.

Okay. Doctor, I've handed you Exhibit 25.

Is that the document that you're referring to in your Appendix I.E?

A. Yes, it appears to be that document.

Q. And do you see that on the very face of -- can you see that on the very face of that document it indicates it's not an Allergan or an Actavis document, but rather an Alpharma document?

A. Yes, I do see that.

Q. And this is one of the five documents you considered in part of forming your opinions about Allergan, right?

A. Yes.

Q. So really there are only, at most, four documents that were actually Allergan documents that you considered, right?

MR. ARBITBLIT: Object to form. Calls for a legal conclusion. Argumentative.

THE WITNESS: My understanding was that these were all Allergan documents.

QUESTIONS BY MR. STAMPFL:

Q. Though this one says on its face it's an Alpharma document, right?

MR. ARBITBLIT: Object to form.

THE WITNESS: It does say that on the face.

QUESTIONS BY MR. STAMPFL:

Q. Did you review these documents before you wrote your report?

A. Yes.

MR. STAMPFL: I will concede my

time and pass the witness. Thank you.

THE WITNESS: You're welcome.

VIDEOGRAPHER: We're now going off the record, and the time is 4:36 p.m.

(Off the record at 4:36 p.m.)

VIDEOGRAPHER: We are now going back on the record, and the time is 4:47 p.m.

CROSS-EXAMINATION

QUESTIONS BY MS. VICARI:

Q. Good afternoon, Dr. Lembke. My name is Angela Vicari, and I am with the law firm of Arnold and Porter, and I represent Endo Pharmaceuticals, Inc., The Health Solutions, Inc., and I also represent Par Pharmaceutical, Inc., in this case.

Dr. Lembke, your report makes no reference to Par, so you're not offering any opinions in this case as to Par Pharmaceutical, correct?

MR. ARBITBLIT: Objection. Calls for a legal conclusion.

THE WITNESS: So one thing that I am not aware of is the various

acquisitions of one company by another.

So maybe you could clarify for me is -- was Par acquired by Endo? I can't really speak to that. I can speak to my knowledge of the actions of Endo based on the documents that I have reviewed and my broader knowledge of the causality in the opioid epidemic.

QUESTIONS BY MS. VICARI:

Q. Are you aware of any promotional activities by Par Pharmaceutical, Inc.?

A. What opioid does Par Pharmaceutical, Inc., manufacture?

Q. Sitting here today, you don't know what opioids Par Pharmaceutical, Inc., manufactures, correct?

A. No.

Q. And if you don't know what pharmaceutical medications Par Pharmaceutical, Inc., makes, you can't make any -- you can't issue any opinions to a reasonable degree of medical certainty about

any marketing or promotional activities that Par engaged in, correct?

MR. ARBITBLIT: Object to form. Legal conclusion.

THE WITNESS: I haven't reviewed specific promotional documents for Par Pharmaceuticals.

QUESTIONS BY MS. VICARI:

Q. Dr. Lembke, do you recall ever prescribing Opana to a patient?

A. I don't specifically recall prescribing Opana, but I may have done over the years.

Q. Okay. Do you recall prescribing original Opana ER to a patient?

A. I may have done, but I don't recall specifically prescribing that.

Q. Do you recall prescribing a reformulated Opana ER to a patient?

A. I don't have a specific recollection.

Q. And do you recall ever prescribing Percocet to a patient?

A. I don't have a specific recollection of prescribing a specific opioid

over the years.

Q. Do you have a recollection of prescribing any other Endo opioid medications to a patient?

A. No.

Q. In your opinion, have you ever prescribed an Endo opioid where an opioid was not medically necessary?

A. So in my opinion, the practice of prescribing opioids for the treatment of chronic pain is not evidence-based and, therefore, not medically necessary.

Q. Okay. Thank you.

My question was: Have you ever prescribed an Endo opioid where it was not medically necessary?

A. I don't have a specific recollection of prescribing Endo, so I can't speak to the medical necessity.

Q. Dr. Lembke, are you aware of any doctors who have safely and effectively prescribed opioids to treat chronic pain?

MR. ARBITBLIT: Object to form.

THE WITNESS: I am aware of lots of doctors who claim that their

prescribing of opioids in the treatment of chronic pain is effective, but I believe that they have been misinformed and do not fully appreciate the risks involved.

QUESTIONS BY MS. VICARI:

Q. Do you believe that there is a way for doctors to safely and prescribe -- strike that.

Is there a way for doctors to safely and effectively prescribe opioids to treat chronic pain?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think there may be rare exceptions in which that's true, but for the vast majority of patients, I don't believe that opioids for chronic pain are either safe or effective, and nor is it supported by the evidence.

QUESTIONS BY MS. VICARI:

Q. You're not saying that the prescription of opioids for the treatment of chronic pain is malpractice, are you?

MR. ARBITBLIT: Object to form.

THE WITNESS: I'm not saying it's malpractice. In fact, I would say that doctors have been duped and so are not responsible for the ways in which they have been prescribing, despite the lack of evidence to support the use of opioids in the treatment of chronic pain.

QUESTIONS BY MS. VICARI:

Q. And do you believe that even as -- sitting here today --

MR. ARBITBLIT: Object to form.

QUESTIONS BY MS. VICARI:

Q. -- it's currently being prescribed?

MR. ARBITBLIT: Object to form.

THE WITNESS: I believe that there are physicians who continue to lack a full understanding of the evidence regarding benefit and risks of opioids in the treatment of chronic pain.

QUESTIONS BY MS. VICARI:

Q. What steps can a doctor take to safely and effectively prescribe opioids to

treat chronic pain?

MR. ARBITBLIT: Object to form. Argumentative. Assumes facts not in evidence. Misstates the testimony.

THE WITNESS: Yeah, so your question assumes that opioids are an effective treatment for chronic pain, and the evidence doesn't support that.

QUESTIONS BY MS. VICARI:

Q. Is every prescription of opioids written for chronic noncancer pain not medically necessary?

MR. ARBITBLIT: Object to form.

THE WITNESS: There's no evidence to support the benefit of opioids in the treatment of chronic pain.

QUESTIONS BY MS. VICARI:

Q. Is it your opinion that Endo's engaging in misleading promotion of opioids today?

MR. ARBITBLIT: Object to form.

THE WITNESS: I believe that the problem of the defendants manipulating and misrepresenting the

evidence to promote opioid prescribing is a problem that continues to this day.

QUESTIONS BY MS. VICARI:

Q. Okay. That wasn't my question. My question was very specific to Endo.

Is it your opinion that Endo is engaging in misleading promotion of opioids today?

A. Yes.

Q. Okay. And is it your opinion is that Endo is miseducating doctors, even today?

A. Yes.

Q. What is your basis for saying that Endo is engaging -- or that Endo is engaging in misleading promotion of opioids today?

A. I believe that the defendants still fail to acknowledge the weight of the evidence that is insufficient and weak with regards to the use of opioids in the treatment of chronic pain, and still fail to recognize the very high risk of addiction, even when patients are prescribed opioids by

a doctor for the treatment of chronic pain.

Q. Can you tell me what promotional activities Endo is engaged in today?

A. I believe that the false messaging that is in my report continues generally today.

Q. My question was very specific to Endo.

Can you tell me what promotional activities Endo is engaged in today?

A. I think that the extent of the impact of the defendants' false messaging is so profound and wide-reaching that in order to really constitute an end to that false messaging, it would require opioid manufacturers to come out and boldly acknowledge the ways in which they have falsely promoted those messages and work to correct those false statements and false marketing.

And failure to do so, in my opinion, constitutes continued implicit marketing of older messages.

Q. So the marketing you're talking about today is implicit marketing?

A. Much of it is covert and implicit, and that's one of the major arguments that I make in my report is the way that opioid manufacturers have infiltrated key opinion leaders and watchdog organizations inside of medicine to give the impression that these marketing messages are based in science, when, in fact, that's not the case.

Q. Dr. Lembke, all the documents that you considered in forming your opinions as to Endo are set forth in Exhibit B to your report and in the supplement that plaintiffs' counsel I believe sent to defense counsel on April 22nd; is that correct?

A. Yes.

Q. Okay. You didn't consider any deposition testimony given by Endo witnesses, did you?

A. No.

Q. And you didn't consider any deposition testimony given by Par witnesses, did you?

A. No.
Q. And you didn't review all of Endo's marketing materials, did you?
A. No.
Q. And you didn't consider all of Endo's marketing materials in issuing your opinions in this case, correct?
A. That's correct.
Q. And you're not offering an opinion on Endo marketing materials that aren't listed in Exhibit B to your report or in the supplement that we received from plaintiffs' counsel, correct?
A. That's correct.
Q. And you're not offering an opinion on any studies that were sponsored by Endo that aren't listed in Exhibit B to your report or in the 4/22 supplement that we received from plaintiffs' counsel, correct?
MR. ARBITBLIT: Include -- are you including what she's mentioned in her report itself?
MS. VICARI: Well, if it's in her report, she considered it, and it's in Exhibit B. Correct, Counsel?

MR. ARBITBLIT: Yes.
MS. VICARI: You know what? I'm talking about Exhibit B. I'll repeat my question.
QUESTIONS BY MS. VICARI:
Q. You're not offering an opinion on any studies that were sponsored by Endo that aren't listed in Exhibit B or in the 4/22 supplement?
A. That's correct.
Q. And you're not offering an opinion on any statements by Endo that aren't in documents that are listed in Exhibit B or in the 4/22 supplement, correct?
A. That's correct.
Q. And all the opinions that you intend to offer at trial are included in your report, correct?
A. Yes, unless there are additional documents that you would like me to review. I would be happy to do that.
Q. You don't intend to offer opinions at trial that aren't in your report, correct?
A. That's correct.

Q. Now, you in appendix -- in the appendix of your report, you have a five-page section in which you refer to Endo Pharmaceuticals, correct?
I believe it's Exhibit 13?
A. Yes.
Q. Okay. And in those five pages, Section 1.D, you cite several Endo documents and studies, correct?
A. I'm not finding 1.D.
Q. If you hand me Exhibit 13, I had left it open on your stack of exhibits next to you.
A. Oh, I see, yes. I do see that, the D.
Q. Exhibit 13, Section 1.D, correct?
A. Yes, I was looking at the letters.
Q. And in those five pages, we'll call it the Endo section of your report, you cite several Endo documents and studies, correct?
A. That's right.
Q. Can you identify any doctors in

Cuyahoga and Summit County who actually read the documents you cite in those pages of your report?
MR. ARBITBLIT: Object to form.
THE WITNESS: I cannot cite specific doctors, but this was a wide-ranging campaign on the part of Endo and other defendants, so I'm confident that providers in Summit and Cuyahoga County were exposed to this false messaging.
QUESTIONS BY MS. VICARI:
Q. My question wasn't about false messaging generally. Very specific question.
You can't identify any doctors in Cuyahoga or Summit County who read the documents that you cite on those five pages of your report?
MR. ARBITBLIT: Objection. Argumentative.
THE WITNESS: I can't cite specific doctors.
QUESTIONS BY MS. VICARI:
Q. And you can't cite specific doctors who relied on any of the specific

documents that you cite in those five pages of your report, correct?

A. I would be very surprised if doctors in Cuyahoga and Summit Counties had not been exposed to this misleading marketing as it was a national campaign, and we were all exposed to it, and it caused the paradigm shift that changed the way that opioids are prescribed in this country.

Q. Thank you, Doctor.

I was talking about the specific documents that you cite in those five pages.

A. Uh-huh.

Q. You can't identify any doctors in Cuyahoga or Summit County who relied on those documents that you cite in those five pages of your report, correct?

MR. ARBITBLIT: Objection. Objection. Argumentative. Misstates.

THE WITNESS: I feel like I answered the question to the best of my ability.

QUESTIONS BY MS. VICARI:

Q. You can't say that any patient

in Summit or Cuyahoga County who was prescribed an Endo opioid medication would not have been prescribed a different opioid if Endo did not market opioids, correct?

A. Oh, can you rephrase that? Sorry.

Q. You can't say that any patient in Summit or Cuyahoga County who was prescribed an Endo opioid would not otherwise have been prescribed an opioid if Endo did not market opioid products?

MR. ARBITBLIT: Objection. Speculative.

THE WITNESS: I guess I'm going to ask you to rephrase the question. I'm having trouble understanding it.

QUESTIONS BY MS. VICARI:

Q. Patients in Summit and Cuyahoga Counties were prescribed opioids?

A. Correct.

Q. And some were prescribed Endo opioids, correct?

A. Yes.

Q. And if Endo opioids weren't available to those patients, you can't say

that those patients would not have otherwise been prescribed a different opioid product, correct?

MR. ARBITBLIT: Objection. Speculative.

THE WITNESS: It's hard for me to know if they hadn't been prescribed Endo, whether or not they would have been prescribed some other opioid.

QUESTIONS BY MS. VICARI:

Q. It depends on the individual patient and the individual doctor, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: Again, it's very hard for me to speculate on that type of scenario.

QUESTIONS BY MS. VICARI:

Q. You would be speculating because it's an individualized inquiry, right?

MR. ARBITBLIT: Object to form. Misstates.

QUESTIONS BY MS. VICARI:

Q. You can answer the question.

A. Can you rephrase it?

Q. I said you would be speculating because it's an individualized inquiry, correct?

MR. ARBITBLIT: Object to form.

THE WITNESS: Can you rephrase your question? Sorry.

QUESTIONS BY MS. VICARI:

Q. You would be speculating because it depends on the patient, right?

MR. ARBITBLIT: Object to form.

THE WITNESS: I think it's just speculative, and so it's hard for me to answer.

QUESTIONS BY MS. VICARI:

Q. You would agree with me that there are nonopioid medications that can treat pain, right?

A. Yes.

Q. Okay. And you would agree with me that all medications are accompanied with risks of some sort?

A. Yes.

Q. Okay. And acetaminophen is a drug that can be used to treat pain, correct?

A. Yes.

Q. And but you would agree with me that treatment with acetaminophen is not appropriate in all patients, right?
A. Yes.
Q. And you would agree with me that treatment with NSAIDs is not appropriate in all patients, right?
A. Yes.
Q. Dr. Lembke, you don't have an opinion about whether Endo violated any FDA regulations concerning pharmaceutical marketing, correct?
A. There are other experts who will testify regarding the FDA. I was not asked to provide an opinion on that.
Q. Dr. Lembke, on page 55 of your report, you cite a study by McIlwain, and you note that Endo sponsored that study.
My only question to you is whether you can identify any physicians in Summit or Cuyahoga County who read the McIlwain study?
MR. ARBITBLIT: Object to form.
THE WITNESS: I can't speak to individual physicians, but I do think

that the Cochrane analysis had a huge impact on physicians' perception of risk --
QUESTIONS BY MS. VICARI:
Q. I didn't ask about the Cochrane analysis. I have limited time. I asked about the McIlwain study.
MR. ARBITBLIT: Limited time or not, Counsel, you're supposed to let her finish.
THE WITNESS: I think I did answer it.
QUESTIONS BY MS. VICARI:
Q. You can't identify any physicians, correct?
MR. ARBITBLIT: Object to form.
THE WITNESS: Again, I think that I've answered this before in other ways, with other defendants asking similar questions, that although I don't -- I can't identify any specific physicians. Broadly this is misleading marketing messages. We were all exposed to them in the '90s and ongoing to today.

And it had a significant and instrumental effect on the way that we prescribe opioids.
QUESTIONS BY MS. VICARI:
Q. Dr. Lembke, you would agree with me that as a general matter, a patient's exposure to an ineffective medical treatment should be minimized, correct?
MR. ARBITBLIT: Object to form. Incomplete hypothetical.
THE WITNESS: It says here -- can you restate because it says "shouldn't be minimized." But I think you meant should be minimized.
QUESTIONS BY MS. VICARI:
Q. That is a mistake in the transcript.
You would agree with me that a patient's exposure to an ineffective medical treatment should be minimized?
MR. ARBITBLIT: Object to form.
THE WITNESS: I do agree with that.
MS. VICARI: Thank you. I have no further questions. We can go off

the record. I'll pass the witness.
VIDEOGRAPHER: We're now going off the record, and the time is 5:07 p.m.
(Off the record at 5:07 p.m.)
VIDEOGRAPHER: We're now going back on the record, and the time is 5:08 p.m.
CROSS-EXAMINATION
QUESTIONS BY MS. HOLLY:
Q. My name is Pam Holly. I'm an attorney with Morgan Lewis, and we represent Teva Pharmaceuticals, USA, Cephalon, Inc., Actavis Pharma, Watson Laboratories and Actavis, LLC.
Are you familiar -- or are you aware that Watson Laboratories is a party to this action?
A. I was not aware.
Q. Is it fair to say that you don't know what opioid medications they sell?
A. I know what opioids Teva Pharmaceuticals sells, so if that's all part of the same entity, Actiq and Fentora.
Q. So is it fair to say that you

don't know what opioids Watson Labs sells, correct?

A. Correct.

Q. Are you aware that Actavis Pharma is a part of this litigation?

A. I believe that Actavis Pharma was mentioned in combination with Allergan.

Q. A different entity, not Actavis Pharma.

A. Okay. Okay.

Q. So it's fair to say that you're not aware that Actavis Pharma is a party to this litigation?

A. It's fair to say that I'm not aware of the various mergers, and it is very confusing. So I'm not entirely aware of who owned what when.

Q. Are you aware that Actavis, LLC, is a party to this litigation?

A. I wasn't aware, but I am aware now.

Q. Are you aware of what opioid medications they sell?

A. No.

Q. Are you aware that generic

manufacturers do not -- excuse me, do not market their products?

A. I wasn't specifically aware of that, no.

Q. Are you aware that Teva Pharmaceuticals USA is a party to this litigation?

A. Yes.

Q. Do you know what products Teva Pharmaceuticals --

A. Actiq and Fentora.

Q. Your report makes no reference to Teva Pharmaceuticals USA, so it's fair to say that you can't offer an opinion to a reasonable degree of medical certainty about the marketing of Teva USA; is that correct?

A. I disagree. If they're named in the complaint, and I see all the defendants as party to the litigation, and --

Q. Any -- pardon me.

A. Go ahead. Go ahead.

Q. I was going to ask you to point me to a reference in your report to Teva Pharmaceuticals USA.

We may have to go off the

record, but I only have five minutes.

A. Sorry. Yeah. There's no specific reference in my report to Teva Pharmaceuticals, but if they're named in the complaint, I believe -- I agree with the complaint, and my report applies to all the defendants in particular as pertains to the misrepresentation of the benefits and risks of opioids more broadly as a class of drugs.

Q. So Appendix I of your report has five sections, correct?

A. Yes.

Q. And none of those five sections relate to Teva Pharmaceuticals or Cephalon, correct?

A. That's correct.

Q. So it's fair to say that in your report, you're not offering an opinion in this litigation about the marketing conducted by those entities, correct?

A. No. I feel like I answered that question already.

Q. Well, I don't -- I disagree with all due respect.

There's no section -- what is

the title of Appendix I?

A. Appendix I?

Q. In the table of contents, you refer to it as misleading promotional messages, correct?

A. Yes.

MR. ARBITBLIT: That's it. Thank you, Counsel. It's been nice. Feel free to take whatever is left over at the end, sandwiches, I mean.

VIDEOGRAPHER: Shall we conclude?

MR. ARBITBLIT: Yes.

VIDEOGRAPHER: Okay. This concludes the video deposition of Anna Lembke. We are --

MS. HOLLY: I'm sorry, I did not have five minutes.

MS. DO AMARAL: You did.

MS. HOLLY: I did not have five minutes.

VIDEOGRAPHER: I have five.

MS. HOLLY: I am --

MR. ARBITBLIT: What does your timer say, Pam? Have you timed

yourself?

MS. HOLLY: Yeah, my time is three minutes.

MS. DO AMARAL: No. No, sorry.

MR. ARBITBLIT: No.

MS. DO AMARAL: Your codefendants, the videographer, and by my count --

MS. HOLLY: All right. I'm going to state for the record that I have specific time to ask questions that I intended to ask on behalf of my clients, and I object and don't agree to close the deposition, and I reserve all rights to raise with the Court to request the appropriate relief, including any deposition testimony that went unanswered here today.

MR. ARBITBLIT: Well, let's do two more minutes, Pam, and ask your questions. Let's not fight about two minutes.

MS. HOLLY: Okay. Well, then I need -- I need -- I need full two minutes.

MR. ARBITBLIT: Calm down.

MS. HOLLY: I need some answers within that time, please.

MR. ARBITBLIT: Well, we're not going to give you answers just to give you answers. If you ask questions, the witness will answer them.

MS. HOLLY: I'm not going to waste time talking about this. I made my objection, and I'm going to continue my examination.

MR. ARBITBLIT: This is not your two minutes. This is discussion about you're claiming that she's not answering your questions, which I disagree. Start your two minutes and ask your questions.

QUESTIONS BY MS. HOLLY:

Q. Are you aware of any marketing statements made by Teva or Cephalon in Summit or Cuyahoga County?

A. I'm not specifically aware of marketing specifically in those counties, but I believe that the misleading promotional statements have disseminated across every

region of the United States, and that Cuyahoga County and Summit County are not exceptions to that.

Q. And what are the misleading statements made by -- contained in your report -- in your opinion in your report by Cephalon and Teva?

A. If they were named in the complaint, and they were, then they participated in the misleading marketing that overstated the benefits and understated the risks.

Q. So your opinion then is based on the complaint allegations as opposed to underlying evidence or documents?

MR. ARBITBLIT: Object to form.

THE WITNESS: My complaint is based on my understanding of the ways in which opioid manufacturers across the board, including all of the defendants named in the complaint, misrepresented the evidence.

QUESTIONS BY MS. HOLLY:

Q. But Exhibit {inaudible} does not contain any documents produced by Teva or

Cephalon, correct?

A. Pardon me?

Q. Exhibit -- your report does not contain any documents produced by Teva or Cephalon; is that correct?

A. I do not have a section in my appendix on Teva or Cephalon.

Q. So what is the basis of your opinion as it relates to Teva and Cephalon if you have nothing in your report that relates to them?

A. I was the recipient of marketing for products made by Teva, including Actiq and Fentora, in my medical training and residency, so I don't need to review specific documents. I've been hearing those messages for two decades.

MR. ARBITBLIT: And that was over two minutes, and we're done.

MS. HOLLY: I renew my objection to the time.

MR. ARBITBLIT: Take it up with your co-counsel. Take it up with your defense counsel. They divided the time.

VIDEOGRAPHER: Okay. We are now concluding the video deposition of Anna Lembke. We are now going off the record, and the time is 5:17 p.m.

(Deposition concluded at 5:17 p.m.)

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CERTIFICATE

I, CARRIE A. CAMPBELL, Registered Diplomate Reporter, Certified Realtime Reporter and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, Anna Lembke, M.D., was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Carrie A. Campbell

CARRIE A. CAMPBELL,
NCRA Registered Diplomate Reporter
Certified Realtime Reporter
Notary Public
Dated: April 29, 2019

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

Anna Lembke, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20 _____.

My commission expires: _____

Notary Public

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ERRATA

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PAGE	LINE	CHANGE/REASON

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LAWYER'S NOTES

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PAGE	LINE	